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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

TRI-VALLEY CARES, MARYLIA KELLEY, JANIS KATE TURNER, and JEDIDJAH DE VRIES,

Plaintiffs,

vs.

UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION, and LAWRENCE LIVERMORE NATIONAL LABORATORY,

Defendants

Case No. 08-cv-01372-SBA

AMENDED PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR PRELIMINARY INJUNCTION; SUPPORTING MEMORANDUM OF POINTS AND AUTHORITIES

and

[PROPOSED] ORDER THEREON

Date: May 6, 2008
Time: 1:00 p.m.
Judge: Hon. Saundra B. Armstrong

NOTICE OF MOTION AND MOTION FOR PRELIMINARY INJUNCTION

TO DEFENDANTS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that plaintiffs Tri-Valley CAREs, Marylia Kelley, Janis Kate Turner, and Jedidjah de Vries (collectively, "Plaintiffs") hereby move the Court for an order granting interlocutory injunctive relief on the grounds that such relief is warranted because Plaintiffs can show both that (1) they are likely to prevail on the merits, and (2) the balance of hardships tips sharply toward Plaintiffs. This Motion is based on: this Notice of Motion and Motion; the accompanying Memorandum of Points and Authorities; the Declarations of Edward Hammond, Marylia Kelley, and Mark Wheelis, Ph.D.; the pleadings and records on file in this matter; and on such argument as counsel may present if the Court orders a hearing on this Motion.

Plaintiffs seek an order barring continued operation of the proposed BSL-3 facility at Lawrence Livermore National Laboratory in Livermore, California, for the reasons set forth below. A proposed order is lodged concurrently.

Dated this 26th day of March, 2008

/S/

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TABLE OF CONTENTS

LIST OF EXHIBITS

Exhibit 1	Declaration of Edward Hammond in Support of Plaintiffs' Motion for Preliminary Injunction
Exhibit 2	Declaration of Marylia Kelley in Support of Plaintiffs' Motion for Preliminary Injunction
Exhibit 3	Declaration of Mark Wheelis, Ph.D. in Support of Plaintiffs' Motion for Preliminary Injunction
Exhibit 4	Department of Energy, Draft Revised Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California (2007)
Exhibit 5	Department of Energy, Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California (2002)
Exhibit 6	Department of Energy, Final Revised Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California (2008)
Exhibit 7	Department of Health and Human Services Office of Inspector General, Fraud Prevention & Detection, Enforcement Actions, Administrative Actions, Civil Monetary Penalties, Select Agents and Toxins http://www.oig.hhs.gov/fraud/enforcement/administrative/cmp/cmpitems.html#6
Exhibit 8	Eric Lipton, *U.S. Called Lax at Policing Labs Handling Biohazards*, N.Y. TIMES, October 5, 2007
Exhibit 9	*Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States: Hearing Before the H. Comm. on Energy and Commerce*, 110th Cong. 1 (2007) (statement of Rep. Bart Stupak, Chairman, Subcomm. on Oversight and Investigations)
Exhibit 10	Jaxon Van Derbeken, *Lab fined $450,000 for mishandling anthrax*, S.F. CHRONICLE, Oct. 7, 2007

Exhibit 11 Jia-Rui Chong, *Experts spell out risks of bioagent program*, L.A. TIMES, October 5, 2007

Exhibit 12 Lawrence Livermore National Laboratory Institutional Biosafety Committee Meeting Minutes (Nov. 16, 2005)

Exhibit 13 Memorandum from the Office of NEPA Policy and Compliance to the DOE NEPA Community (Dec. 1, 2006)

Exhibit 14 MILTON LEITENBERG, ASSESSING THE BIOLOGICAL WEAPONS AND BIOTERRORISM THREAT (2005)

Exhibit 15 The Associated Press, *U.S. Labs Mishandling Deadly Germs*, N.Y. TIMES, October 2, 2007

Exhibit 16 U.S. DEPT. OF ENERGY, ENVIRONMENT, SAFETY AND HEALTH, OFFICE OF NEPA POLICY AND COMPLIANCE, RECOMMENDATIONS FOR ANALYZING ACCIDENTS UNDER THE NATIONAL ENVIRONMENTAL POLICY ACT (July 2002)

Exhibit 17 U.S. GOVERNMENT ACCOUNTABILITY OFFICE, HIGH-CONTAINMENT BIOSAFETY LABORATORIES: PRELIMINARY OBSERVATIONS ON THE OVERSIGHT OF THE PROLIFERATION OF BSL-3 AND BSL-4 LABORATORIES IN THE UNITED STATES, GAO-08-108T (2007)

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Regulations

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Defendants United States Department of Energy ("DOE" or "Department"), National Nuclear Security Administration ("NNSA"), and Lawrence Livermore National Laboratory ("Livermore Lab" or "LLNL") (collectively, "Defendants") have commenced operation of a Biosafety Level 3 ("BSL-3") facility at Lawrence Livermore National Laboratory ("LLNL" or "Livermore Lab") in Livermore, California in violation of the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321 *et seq*. (1975), and applicable laws and regulations.[1]

As a result of prior litigation initiated by Tri-Valley CAREs, et al., the United States Court of Appeals for the Ninth Circuit ordered "DOE to consider whether the threat of terrorist activity [at the proposed BSL-3 facility at Livermore Lab] necessitates the preparation of an Environmental Impact Statement." *Tri-Valley CAREs v. Department of Energy*, No. 04-17232, mem. op. at 4 (9th Cir. 2006). Following the Ninth Circuit's decision, the Department was forced to issue interim guidance on how to address intentional destructive acts in NEPA documents. *See* Exhibit 13 at 1. In response to the Ninth Circuit's ruling and DOE's guidance, NNSA revised the prior Environmental Assessment for the proposed facility to consider the potential impacts of terrorist activity. Exhibit 6 at ii. The interim nature of DOE's guidance, coupled with its reliance on the application of an analysis of accidents to an analysis of the potential consequences of acts of sabotage or terrorism, ensured that the new EA would be inadequate.

To protect the public from the proposed BSL-3 facility's inadequately studied risk of a release of dangerous pathogenic material into the environment as a consequence of terrorist attack, abnormal event, or accident, Plaintiffs move this Court for a preliminary injunction

[1] By stipulation, the parties to this action have agreed to a voluntary limitation on operations in the LLNL BSL-3 facility for a period of sixty (60) days in the hopes that they will have this Court's resolution of this Motion for Preliminary Injunction prior to the expiration of that period. This voluntary limitation on operations is subject to the following conditions: (a) no aerosol testing; (b) no rodent infection experiments; (c) no production, generation, or knowing receipt of genetically modified biological material that would require management of the facility at the BSL-3 level; and (d) the total amount of agents in the facility for which BSL-3 containment is recommended in the 4th Edition of *Biosafety in Microbiological and Biomedical Laboratories* shall not exceed 100 milliliters (ml).

barring continued operation of the facility. A plaintiff is entitled to a preliminary injunction if she demonstrates "*either* '(1) a likelihood of success on the merits and the possibility of irreparable injury; or (2) that serious questions going to the merits were raised and the balance of hardships tips sharply in its favor.'" *Nelson v. NASA*, 2008 U.S. App. LEXIS 498, at *9, 512 F.3d 1132 (9th Cir. 2008) (emphasis added) (quoting *Walczak v. EPL Prolong, Inc.*, 198 F.3d 725, 731 (9th Cir. 1999)). The two prongs are not separate tests, as such, but "rather 'extremes of a single continuum,' so 'the greater the relative hardship to [the party seeking the preliminary injunction], the less probability of success must be shown.'" *Nelson*, 2008 U.S. App. LEXIS 498, at *9 (quoting *Walczak*, 198 F.3d at 731). This motion is made on the grounds that interim injunctive relief is warranted in this case under either of the two applicable standards because Plaintiffs can show both that (1) they are likely to prevail on the merits, and (2) the balance of hardships tips sharply toward Plaintiffs.

II. PLAINTIFFS ARE LIKELY TO PREVAIL ON THE MERITS

Plaintiffs are likely to prevail on the merits of their claims against Defendants. Plaintiffs plead four counts against Defendants in their Complaint: (1) failure to prepare an adequate Environmental Assessment ("EA") and Finding of No Significant Impact ("FONSI"), (2) failure to prepare an Environmental Impact Statement ("EIS"), (3) failure to supplement, and (4) failure to comply with applicable regulations. Because the law and the facts support the above allegations, Plaintiffs are likely to prevail on the merits.

1) Failure to prepare an adequate EA and FONSI

Plaintiffs are likely to prevail on the merits of their claim that the new EA for the proposed BSL-3 facility at Livermore Lab is inadequate and does not support the issuance of a FONSI. Under the Department's NEPA Implementing Procedures,

> DOE shall prepare a FONSI only if the related EA supports the finding that the proposed action will not have a significant effect on the human environment. If a required DOE EA does not support a FONSI, DOE shall prepare an EIS and issue a [Record of Decision ("ROD")] before taking action on the proposal addressed by the EA . . . .

10 C.F.R. § 1021.322(a) (1996).

The Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A) (1966), governs this Court's review of Defendants' actions, conclusions, and findings of fact, which must be set aside "if they are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Ocean Advocates v, United States Army Corps of Eng'rs*, 402 F.3d 846, 858 (9th Cir. 2005) (quoting 5 U.S.C. § 706(2)(A)). Judicial review under the arbitrary and capricious standard is "searching and careful," but a reviewing court is "not empowered to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, 91 S. Ct. 814 (1971), *overruled on other grounds by Califano v. Sanders*, 430 U.S. 99, 105, 97 S. Ct. 980 (1977). This Court "must consider whether the decision was based on a consideration of relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park, Inc.*, 401 U.S. at 416; *see Ariz. Cattle Growers' Ass'n v. United States Fish & Wildlife Serv.*, 273 F.3d 1229, 1236 (9th Cir. 2001) (citations omitted) (A reviewing court "must determine whether the agency articulated a rational connection between the facts found and the choice made."). Reviewing courts "must not 'rubber-stamp . . . administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute.'" *Ariz. Cattle Growers' Ass'n*, 273 F.3d at 1236 (citing *NLRB v. Brown*, 380 U.S. 278, 291-92, 85 S. Ct. 980 (1965)).

NEPA requires agencies to "take a 'hard look' at the environmental consequences before taking a major action." *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 97, 103 S. Ct. 2246 (1983) (quoting *Kleppe v. Sierra Club*, 427 U.S. 390, 410, n. 21, 96 S. Ct. 2718 (1976)). Here, Defendants have failed to take a "hard look" at the environmental consequences of operation of the proposed BSL-3 facility at Livermore Lab. Specifically, the new EA and FONSI for the proposed facility are legally inadequate because the terrorism analysis that was used to support the issuance of the FONSI is grossly deficient. Defendants' failure to prepare a legally adequate EA for the proposed facility is arbitrary and capricious, an abuse of discretion, or contrary to law and constitutes a violation of the APA and NEPA.

i. The terrorism analysis is grossly deficient

In violation of NEPA, Defendants failed to take a "hard look" at whether the threat of terrorist activity at the proposed BSL-3 facility necessitates the preparation of an EIS. Instead, Defendants prepared an inadequate and unsupported analysis of the threat of terrorist attack on the proposed facility, which was then used to support the issuance of a FONSI in lieu of the required EIS. The terrorism analysis is inadequate in the following respects, among others: (1) the terrorism analysis is based on an inapplicable and flawed accident scenario, and (2) the terrorism analysis is unreasonable and unsupported.

The terrorism analysis contained in the new EA for the proposed facility is inadequate because it is based on inapplicable and flawed accident scenario. *See* Exhibit 3 at ¶¶ 13-17. According to the new EA, "the consequences of a malicious act designed to breach containment are bounded by the accidents and natural catastrophic events evaluated in the EA because they would result in a similar loss of containment." Exhibit 6 at 59. However, as DOE itself acknowledged in a 2006 memorandum, applying an analysis of accidents to an analysis of the potential consequences of acts of sabotage or terrorism "may not be adequate for all situations, because *accident scenarios may not fully encompass potential threats posed by intentional destructive acts*." Exhibit 13 at 2 (emphasis added).

According to the Department's recommendations for analyzing accidents under NEPA, "[t]he key to informative accident analysis is to develop *realistic* accident scenarios that address a reasonable range of event probabilities and consequences." Exhibit 16 at 4 (emphasis added). An accident scenario "involves a postulated initiating event followed by a sequence of other events or circumstances that result in adverse consequences." *Id.* at 6. The Department "should consider accident scenarios that represent the range or 'spectrum' of reasonably foreseeable accidents, including low probability/high consequence accidents and higher probability/(usually) lower consequence accidents." *Id.* at 4-5. Significantly, DOE recommendations state that bounding analyses, which were used in the new EA, "may mask differences among alternatives and be less informative about the potential need for mitigation." *Id.* at 5. "Bounding" analyses are utilized by NEPA document preparers to compensate for analytical uncertainty by using conservative approaches that overestimate potential impacts. *Id.*

Unrealistically, the bounding analysis applied by Defendants—a centrifuge accident leading to a release of *Coxiella burnetii*—assumes that the air in the proposed BSL-3 facility would exhaust "to the outside of the building through a stack on the roof after passing through two sets of HEPA [("High Efficiency Particulate Air-Purifying")] filters . . . ." Exhibit 6 at 54. In this regard the bounding analysis is inadequate because, in the event of a terrorist attack resulting in a breach or rupture of the proposed facility's walls, air contained therein would clearly not be subject to HEPA filtration as assumed in the new EA. The scenario applied by Defendants also unreasonably assumes that any released bioagents would be destroyed by heat, fire, sunlight, wind, or *exploding containers of disinfectant*. Exhibit 6 at 51, 59; *see* Exhibit 2 at ¶ 39; Exhibit 3 at ¶ 17. Furthermore, given that approximately 8,000 individuals are employed at the Livermore Lab Main Site, a dense collection of buildings occupying approximately 1.3 square miles (821 acres), Defendants' claim that "[a]dverse health effects to uninvolved workers in adjacent buildings or the public would be extremely unlikely to develop from this scenario" is lacking in credibility. Exhibit 6 at 2, 55; *see* Exhibit 3 at ¶¶ 6-12.

Thus, the accident scenario described above is clearly inapplicable to an analysis of the threat of terrorist attack on the proposed BSL-3 facility at LLNL. As a result, Defendants have failed to take a "hard look" at the environmental consequences of terrorist attack on the proposed facility.

The terrorism analysis contained in the new EA for the proposed facility is also inadequate because it is unreasonable and unsupported. Fundamentally, the terrorism analysis is deficient because it fails to adequately analyze the consequences of a release of pathogenic material on Livermore Lab's employees, the over 81,000 residents of the City of Livermore, and the approximately 7 million individuals living within a 50-mile radius of LLNL. *See* Exhibit 6 at 33, 57-66; Exhibit 3 at ¶¶ 6-12. This glaring oversight is the result of Defendants use of the unrealistic and inapplicable bounding scenario described above, which unreasonably assumes that any released bioagents would be subject to HEPA filtration or destroyed by environmental factors or exploding containers of disinfectant. *See* Exhibit 6 at 51, 54, 59. Also, even assuming arguendo that Defendants' assertion is valid that the heat produced by catastrophic events has the

potential to reduce the consequences of a release of pathogenic material, it is improbable that a terrorist would seek to completely destroy the proposed BSL-3 facility. *Id.* at 59. Instead, such a terrorist would likely attempt to lightly damage the facility so as to result in a loss of containment and release of pathogenic material.

Moreover, Defendants assume that diagnostic testing and medical treatment will be immediately available to those whose health is endangered by a release of deadly bioagents. *See* Exhibit 6 at 60. Defendants fail to consider the strong likelihood that a breach of containment will release multiple types of pathogens—since many different ones may be stored or in use—in unknown concentrations. *See* Exhibit 3 at ¶¶ 16-17. The analysis in the new EA assumes that exposed individuals will be "inoculated to prevent infection or treated to assist in recovery." Exhibit 6 at 60. Since, as Defendants later acknowledge, the bioagents to be handled in the proposed facility "can be extremely difficult to detect and some may not cause illness immediately," this assumption is plainly unreasonable. *Id.* at 62. Defendants also fail to account for the possibility that genetically engineered microorganisms handled in the proposed facility, against which available antibiotics and the environmental factors discussed above may be ineffective, will be released into the environment after a loss of containment, catastrophic or otherwise. *See* Exhibit 3 at ¶ 15.

Furthermore, Defendants' unreasonably attempt to bolster their assertion that the probability of a successful terrorist attack on the proposed facility is very low and is not expected during the life of the facility by claiming that the bioagents to be contained in the facility are readily obtainable from the environment. Exhibit 6 at 58, 62-63. This bald assertion simply does not bear scrutiny. *See* Exhibit 3 at ¶¶ 13-16. According to the new EA, the proposed BSL-3 facility will have the ability to produce biological material (enzymes, DNA, ribonucleic acid, etc.) using infectious agents and genetically modified microorganisms, which could not be obtained from the environment. Exhibit 6 at 7; Exhibit 3 at ¶ 15. The proposed facility would represent a collection of bioagents that could be used as bioweapons, so the comparison to gathering pathogenic material from distributed sources is inappropriate. *See* Exhibit 3 at ¶ 16. Also, the quantity of bioagents at the proposed BSL-3 facility, which could be as high as 50

liters, would exceed those quantities easily collected from animal or plant sources in the field. Exhibit 6 at C-10; *see* Exhibit 2 at ¶ 10. In addition, terrorists may find the proposed BSL-3 facility to be an attractive source of known strains of bioagents with demonstrated human virulence, such as the Vollum strain of anthrax. Exhibit 3 at ¶ 14.

Finally, the Department's recommendations for analyzing accidents under NEPA specify that, "[i]n evaluating the effects of an accident, characterize the degree to which buildings, land, and environmental media would be contaminated, and describe (at least qualitatively) the potential health and environmental effects from such contamination, including direct and indirect effects associated with potential cleanup activities." Exhibit 16 at 12. According to the new EA, "[a]s shown in 2001 [following the anthrax mailings], dramatic human health impacts and economic disruption can result following the release of pathogenic materials." Exhibit 6 at 64. A release of deadly bioagents from the proposed BSL-3 facility could necessitate the cessation of operations at Livermore Lab, the evacuation of nearby residents, and the closure of Interstate 580, which could cause unprecedented economic disruption throughout the San Francisco Bay Area and the United States. *See* Exhibit 2 at ¶ 13. None of these potential effects are evaluated in the terrorism analysis contained in the new EA, despite DOE's own recommendations to the contrary.

In light of the above, it is apparent that Defendants have violated NEPA by failing to take a "hard look" at whether the threat of terrorist activity at the proposed BSL-3 facility necessitates the preparation of an EIS. Accordingly, Plaintiffs are likely to prevail on the merits of this claim.

2) Failure to prepare an EIS

Plaintiffs are likely to prevail on their claim that Defendants violated NEPA by failing to prepare an EIS for the proposed BSL-3 facility at Livermore Lab. The proposed facility is a "major Federal action[] significantly affecting the quality of the human environment, [for which] a detailed statement [on] . . . the environmental impact of the proposed action," an EIS, is required. 42 U.S.C. § 4332(2)(C). If substantial questions are raised as to whether a project *may* cause significant degradation of some human environmental factor, an EIS must be prepared. *Ocean Advocates*, 402 F.3d at 864-65 (emphasis in original) (quoting *Idaho Sporting Cong. v.*

Thomas, 137 F.3d 1146, 1149 (9th Cir. 1998) (citation omitted)). A plaintiff is not required to show that significant effects will in fact occur; it is sufficient to raise substantial questions whether a project *may* have a significant effect. *Ocean Advocates*, 402 F.3d at 865 (quoting *Greenpeace Action v. Franklin*, 14 F.3d 1324, 1332 (9th Cir. 1992)).

As used in NEPA, significance "requires considerations of both context and intensity." 40 C.F.R. § 1508.27 (1979). Context "means that the significance of an action must be analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality[,]" while intensity "refers to the severity of impact." *Id.* at § 1508.27(a-b). The following factors, among others, should be considered in evaluating intensity:

> 1. Impacts that may be both beneficial and adverse. A significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial.
> 2. The degree to which the proposed action affects public health of safety.
> . . .
> 4. The degree to which the effects on the quality of the human environment are likely to he highly controversial.
> 5. The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.
> . . .
> 10. Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.

Id. at § 1508.27(b).

Regarding context, operation of the proposed facility may have significant impacts at the local, regional, and national levels. Most obviously, a release of pathogenic material from the proposed BSL-3 facility could result in the exposure of a large number of individuals at LLNL and the surrounding communities. *See* Exhibit 2 at ¶¶ 11-13; Exhibit 3 at ¶¶ 10-11,17. Given Livermore Lab's close proximity to Interstate 580 and the San Francisco Bay Area, such a release could also have significant regional impacts. *See* Exhibit 3 at ¶ 13. Finally, as evidenced by the significant disruptions occasioned by the anthrax mailings in 2001, an accidental release, a terrorist attack on the proposed facility, or the theft and subsequent release of pathogenic material from the facility could have significant impacts nationally as well.

Under similar circumstances, the Department has determined that "preparation of an EIS is the appropriate level of NEPA analysis for the operation of the BSL-3" laboratory at Los

Alamos National Laboratory (LANL) in Los Alamos, New Mexico. Notice of Intent To Prepare an Environmental Impact Statement for the Operation of a Biosafety Level 3 Facility at Los Alamos National Laboratory, Los Alamos, NM, 70 Fed. Reg. 71490 (Nov. 29, 2005). The issues to be analyzed in the LANL EIS include "[a]dditional seismic analysis; safety of laboratory operations; public health and safety; handling, collection, treatment, and disposal of research wastes; other risks; pollution prevention; and potential impacts on air quality, biological resources, cultural resources, water resources, land use, and socioeconomic resources." *Id.*

Given the unique status of both LLNL and LANL as the nation's classified nuclear weapons design laboratories, there is no rational basis for preparing an EIS for the operation of the BSL-3 facility at Los Alamos and not Lawrence Livermore; the same issues which necessitated the preparation of an EIS for the LANL BSL-3 facility are equally applicable to the LLNL BSL-3 facility, if not more so. *See* Exhibit 2 at ¶ 47. For instance, "NNSA determined that it was necessary to conduct additional seismic analysis" concerning the Los Alamos BSL-3 laboratory and not the Lawrence Livermore BSL-3 laboratory, despite the presence of an earthquake fault zone less than 200 feet from the LLNL site boundary. 70 Fed. Reg. 71490; Exhibit 2 at ¶ 36. Moreover, the Livermore Lab Main Site is located in an urban region, in close proximity to residential housing and a busy interstate freeway, so the risks to the human environment are even greater than at Los Alamos. Exhibit 2 at ¶¶ 11-13, 47.

The proposed BSL-3 facility at Livermore Lab may significantly affect the quality of the human environment in the following respects, among others: (i) operation of the proposed facility may affect public health and safety; (ii) the possible effects on the quality of the human environment from operation of the proposed facility are highly controversial; (iii) the possible effects on the human environment from operation of the proposed facility are highly uncertain and involve unique or unknown risks; and (iv) the proposed action, operation of a BSL-3 facility at Livermore Lab for biodefense purposes, threatens a violation of the Biological Weapons Convention, to which the United States is a State Party. Accordingly, Defendants' approval of the new EA and FONSI for the proposed BSL-3 facility is arbitrary and capricious, an abuse of

discretion, or contrary to law and constitutes a violation of the APA and NEPA because Defendants were required to prepare an EIS for the proposed facility.

i. Operation of the proposed facility may affect public health and safety

Operation of the proposed BSL-3 facility at LLNL, including the inadequately studied risks of terrorist attack, accidents, earthquake, and fire, has the potential to cause significant impacts to public health and safety. *See* Exhibit 2 at ¶ 10; Exhibit 3 at ¶¶ 7-17. To put things in perspective, the proposed facility will be located at the Livermore Lab Main Site, which occupies a total area of approximately 1.3 sq. miles (821 acres) and where approximately 8,000 individuals are employed. Exhibit 6 at 2. LLNL is located just outside the boundary of the City of Livermore and about 40 miles east of San Francisco at the southeast end of the Livermore Valley in Alameda County. *Id.* The nearest member of the public is about one-half mile away, and the City of Livermore's central business district is approximately three miles to the west. *Id.* at 2, 55. In 2000, "there were approximately 1.3 million people living in Alameda County . . . and about 6.9 million people living within a 50-mile radius of LLNL[.]" *Id.* at 33.

In the event of a release of deadly bioagents from the proposed facility as a result of terrorist attack, abnormal event, or accident, catastrophic impacts to public health and safety may result. *See* Exhibit 2 at ¶ 10; Exhibit 3 at ¶¶ 7-17. As stated in the new EA, operations or activities to be conducted in the proposed facility could "place up to 1 liter quantities of a slurry of material containing pathogenic organisms at risk at any point in time. One liter of *C. burnetti* generated in tissue culture would contain a maximum of about 1 trillion bacteria." Exhibit 6 at 59. The Centers for Disease Control and Prevention has reported that "exposure to only 10 microorganisms can cause an individual with normal immunocompetency to develop symptoms of disease[,]" and others have reported "this to be as low as five microorganisms or possibly even one[.]" *Id.* at 53. Thus, a loss of containment of pathogenic material during normal operations may result in the release of 100,000,000 infective doses. *See* Exhibit 1 at ¶ 12; Exhibit 2 at ¶ 46. Such a release would almost certainly cause irreparable harm to public health and safety.

Furthermore, the proposed facility is designed to handle operations involving small-animal testing of bioagents and biotoxins, in which up to 100 rodents would be exposed to aerosolized pathogenic material. Exhibit 6 at 7, 20. Because the proposed BSL-3 facility will handle agents that may cause serious or lethal disease as a result of exposure by the inhalation route, aerosolization increases the risks to public health and safety due to accidental occupational exposure and, in the case of a loss of containment, exposure of individuals outside LLNL. Exhibit 3 at ¶ 6.

ii. The possible effects on the human environment are highly controversial

The possible effects on the quality of the human environment from operation of the proposed facility are highly controversial. A proposed action "is highly controversial when there is 'a substantial dispute [about] the size, nature, or effect of the major Federal action rather than the existence of opposition to a use.'" *Anderson v. Evans*, 371 F.3d 475, 489 (9th Cir. 2004) (quoting *Blue Mts. Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1212 (9th Cir. 1998) (citation omitted)). Here, there are substantial disputes regarding the need for the proposed facility, the consequences of an accidental or deliberate release of pathogenic material from the facility, as well as the proposed action's compliance with the Biological Weapons Convention. *See* Exhibit 1 at ¶¶ 4-21; Exhibit 2 at ¶¶ 36-40; Exhibit 3 at ¶¶ 7-24.

iii. The possible effects on the human environment are highly uncertain and involve unique or unknown risks

The possible effects on the human environment from operation of the proposed BSL-3 facility are highly uncertain and involve unique or unknown risks. An agency "must generally prepare an EIS if the environmental effects of a proposed agency action are highly uncertain." *National Parks & Conservation Ass'n v. Babbitt*, 241 F.3d 722, 731-32 (9th Cir. 2001) (citing *Blue Mts. Biodiversity Project*, 161 F.3d at 1212). Preparation of an EIS "is mandated where uncertainty may be resolved by further collection of data," or "where the collection of such data may prevent 'speculation on potential . . . effects. The purpose of an EIS is to obviate the need for speculation by insuring that available data are gathered and analyzed prior to the

implementation of the proposed action.'" *National Parks & Conservation Ass'n*, 241 F.3d at 732 (citing *Blue Mts. Biodiversity Project*, 161 F.3d at 1213-14; quoting *Sierra Club v. United States Forest Service*, 843 F.2d 1190, 1194 (9th Cir. 1988)).

In this case, the possible effects on the human environment from operation of the proposed facility are highly uncertain because there is no precedent for a release of pathogenic material from such a facility in the United States. Exhibit 6 at 52. Although Defendants attempt to use this historical evidence to justify their failure to consider the consequences of such a release, the Ninth Circuit has clearly indicated that incidents of this nature are not so remote and highly speculative as to be beyond NEPA's requirements. *See Tri-Valley CAREs*, No. 04-17232, mem. op. at 4; *San Luis Obispo Mothers for Peace v. NRC*, 449 F.3d 1016, 1030 (9th Cir. 2006). Moreover, on April 2, 1979, an accidental anthrax release occurred at a military microbiology facility at Sverdlovsk, in the former Soviet Union. Exhibit 3 at ¶¶ 7-9. Over 100 people died as a result of this incident, which was caused by operator error in removing a HEPA filter and not replacing it. *Id.* at ¶ 8. Furthermore, since the proposed BSL-3 facility will handle bioagents that could have offensive uses as bioweapons, and potentially genetically modified versions thereof, the proposed action involves unique or unknown risks to the human environment. Exhibit 6 at ii, 18; *see* Exhibit 3 at ¶ 15.

iv. The proposed action threatens a violation of the Biological Weapons Convention

The proposed action, operation of a BSL-3 facility at LLNL for biodefense purposes, threatens a violation of the Biological Weapons Convention ("BWC"), to which the United States is a State Party. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction ("BWC"), Mar. 26, 1975, 26 U.S.T. 583, 1015 U.N.T.S. 163. Pursuant to Article I of the BWC, each State Party "undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain . . . microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes[.]" *Id.* at art. I.

Given that the proposed BSL-3 facility may contain up to 50 liters (or 25,000 vials) of pathogenic material and that research to be conducted therein may involve aerosolization and genetic manipulation of bioagents and biotoxins, there are substantial questions as to whether the proposed action may transgress the BWC. Exhibit 6 at 7, C-10; *see* Exhibit 1 at ¶¶ 11-16; Exhibit 2 at ¶ 38; Exhibit 3 at ¶¶ 18-24. Moreover, although Defendants claim that Livermore Lab's management will ensure compliance with the Convention, there is no indication as to what expertise LLNL's management brings to bear to this matter or what criteria would guide these determinations. *See* Exhibit 6 at 18. Since compliance with the BWC is a difficult issue even for experts in the field, these words ring hollow, particularly in light of Defendants' failure to provide any information as to how compliance would be instituted after public comments explicitly raised such concerns during the public comment periods for both EAs. *See* Exhibit 3 at ¶ 19; Exhibit 5 at C-7-8; Exhibit 6 at C-10-11.

Even though the research to be conducted in the proposed BSL-3 facility at LLNL would be "directed to developing technologies and systems to improve national defense against, and mitigate the consequences of . . . terrorist attacks[,]" Defendants cannot use the presupposed benefits of this research to override the significant effects that may result from operation of the proposed facility and which necessitate the preparation of an EIS. Exhibit 6 at 56-57. As specified above, "[a] significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial." 40 C.F.R. § 1508.27(b)(1).

Accordingly, Plaintiffs are likely to prevail on their claim that Defendants violated NEPA by failing to prepare an EIS for the proposed BSL-3 facility at Livermore Lab.

3) Failure to supplement

Plaintiffs are likely to prevail on their claim that Defendants violated applicable regulations implementing NEPA by failing to prepare a supplement to the new EA in response to significant new circumstances and information relevant to the environmental impacts of the proposed facility that became publicly available only after the new EA was circulated for public review and comment. Moreover, there are indications that Defendants deliberately withheld some of this information until after the public comment period had ended. Defendants' failure to

prepare a supplement to the new EA for the proposed facility is arbitrary and capricious, an abuse of discretion, or contrary to law and constitutes a violation of the APA and NEPA.

Federal agencies have "a continuing duty to gather and evaluate new information relevant to the environmental impact of [the agencies'] actions." *Warm Springs Dam Task Force v. Gribble*, 621 F.2d 1017, 1024 (9th Cir. 1980) (citing 42 U.S.C. § 4332(2)(A-B) (1975)); *Essex County Preservation Ass'n v. Campbell*, 536 F.2d 956, 960-61 (1st Cir. 1976); *Society for Animal Rights, Inc. v. Schlesinger*, 512 F.2d 915, 917-18 (D.C.Cir.1975)). Pursuant to the Department's regulations implementing NEPA, "DOE shall prepare a supplemental EIS if there are . . . significant new circumstances or information relevant to environmental concerns," as discussed in the NEPA regulations promulgated by CEQ. 10 C.F.R. § 1021.314(a) (1992). Under CEQ's regulations, agencies shall prepare supplements to either draft or final EISs if "[t]here are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts." 40 C.F.R. § 1509(c)(1)(ii) (1978). The Supreme Court has interpreted NEPA, in light of this regulation, as requiring an agency to take a "hard look" at new circumstances and information to determine whether supplementation may be required. *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 72-73, 124 S. Ct. 2373 (2004) (citing *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 378-85, 109 S. Ct. 1851 (1989)).

Although the instant action concerns supplementation of an EA, the standard for supplementing an EA is the same as for an EIS. *Idaho Sporting Congress, Inc. v. Alexander*, 222 F.3d 562, 566 n.2 (9th Cir. 2000) (citations omitted); *see Price Rd. Neighborhood Ass'n v. United States DOT*, 113 F.3d 1505, 1509-10 (9th Cir. 1997); *Friends of the Bow v. Thompson*, 124 F.3d 1210, 1218 n.3 (10th Cir. 1997) (citations omitted); *Clinch Coalition v. Damon*, 316 F. Supp. 2d 364, 376 (D. Va. 2004) (citations omitted).

The following significant new circumstances and information relevant to environmental concerns and bearing on the proposed action and its impacts require supplementation of the new EA for the proposed BSL-3 facility at LLNL: (i) the Livermore Lab anthrax release in August-September 2005; (ii) information regarding the safety and security of BSL-3 facilities; (iii) a

report on the proliferation of high-containment biosafety laboratories; (iv) a hearing in Congress on the proliferation of high-containment biosafety laboratories; and (v) a report assessing the biological weapons and bioterrorism threat.

i. Livermore Lab anthrax release

In August-September 2005, while the prior lawsuit filed by Tri-Valley CAREs, et al. regarding the LLNL BSL-3 facility was pending in the Court of Appeals for the Ninth Circuit, Livermore Lab was responsible for an anthrax release. *See* Exhibit 6 at 56-57; Exhibit 1 at ¶ 18; Exhibit 2 at ¶¶ 21-26; Exhibit 3 at ¶ 12. Defendants failed to inform either the court or Plaintiffs of this incident, which was relevant to the issues under consideration in the litigation. *See* Exhibit 1 at ¶ 18; Exhibit 2 at ¶ 24. Although the anthrax release was briefly described in the draft of the new EA, that description omitted important details and downplayed the significance of the incident. *See* Exhibit 4 at 57. For instance, there was no mention that anthrax was involved, that the anthrax was packaged by an unauthorized individual, or that LLNL's Responsible Official—the individual designated by Livermore Lab with the authority to ensure compliance with the select agent[2] regulations—failed to ensure such compliance. *See id.* Instead, Defendants misleadingly attempted to characterize the anthrax release as a minor violation of Department of Transportation ("DOT") shipping and packaging requirements. *See* Exhibit 4 at 57; Exhibit 2 at ¶ 25.

On September 24, 2007, the Regents of the University of California, as the manager of Livermore Lab, agreed to resolve its liability for the anthrax release. Exhibit 7. The HHS Office of Inspector General ("OIG") "alleged that LLNL transferred vials of anthrax to two laboratories located in Florida and Virginia." *Id.* During the transfers, anthrax was released from the approximately 4,000 shipped vials because the scientist who packaged the shipments "left the twist caps off two containers" and a third vial had a loose cap. *Id.*; Exhibit 10. Fiver workers were exposed to anthrax while unpacking the shipments and required medical treatment. Exhibit

[2] Select agents are bioagents "of human disease whose transfer or receipt requires a facility to be registered with the [Centers for Disease Control and Prevention] under 42 CFR Part 72.6; select agents have historically been associated with weaponizing efforts." Exhibit 6 at 18.

6 at 56. As a result of this incident, CDC suspended all LLNL transfers of select agents, and Livermore Lab issued a full stand-down of all select agent work. *Id.* CDC sent LLNL a report listing twenty-nine (29) points that needed to be addressed. Exhibit 12 at 5.

Specifically, the OIG alleged that Livermore Lab failed to comply with security and access requirements by allowing an individual not authorized to have access to select agents to package the shipments of anthrax. Exhibit 7. The OIG also alleged that Livermore Lab violated the transfer requirements of the select agent regulations by failing to comply with applicable shipping and packaging laws when transferring a select agent. *Id.* Finally, the OIG alleged that LLNL's Responsible Official failed to ensure compliance with the shipping and packaging requirements of the select agent regulations. *Id.* Under the terms of the settlement, Livermore Lab agreed to pay the OIG $450,000 to resolve these allegations. *Id.*

The LLNL anthrax release is significant because it highlights and validates concerns expressed by Plaintiffs and the Ninth Circuit with regard to the threat of terrorist attack on the proposed BSL-3 facility. *See* Exhibit 2 at ¶ 23. As specified above, the OIG alleged that Livermore Lab failed to comply with security and access requirements by allowing an unauthorized individual to have access to select agents. Exhibit 6 at 57. This runs directly counter to the assertion in the new EA that "[o]nly personnel on LLNL's CDC registration are allowed to handle [select] agents." *Id.* at 65. After acknowledging that "the theft of pathogenic materials by an insider . . . could have very serious consequences," Defendants concluded that "this scenario is not expected to occur at LLNL due to human reliability programs, security procedures, and management controls at the facility and the laboratory." *Id.* at 66. With regard to the anthrax release, both the security procedures and management controls failed. *See id.* at 56-57.

Although Livermore Lab rightfully instituted multiple corrective actions in response to the anthrax release, Defendants' lack of candor regarding the incident in both the earlier litigation and the draft version of the new EA effectively circumvented judicial review and public comment under NEPA. *See* Exhibit 6 at 56; Exhibit 1 at ¶ 18; Exhibit 2 at ¶¶ 24-26. Under CEQ's regulations, agencies are required to "prepare, circulate, and file a supplement . . .

in the same fashion (exclusive of scoping) as a draft and final [EIS,]" which Defendants have not done. 40 C.F.R. § 1502.9(c)(4) (1978). Thus, because the final version of the new EA containing significant new information regarding the anthrax release was not circulated for public comment, Defendants have failed to comply with NEPA.

ii. Information regarding the safety and security of BSL-3 facilities

After the completion of the public review and comment period on the draft of the new EA, a report by the Associated Press indicated that BSL-3 and BSL-4 laboratories in the United States "have experienced more than 100 accidents and missing shipments since 2003, and the number is increasing steadily as more labs across the country are approved to do the work." Exhibit 15; *see* Exhibit 1 at ¶¶ 18-20. While these mishaps are too numerous to list here in any detail, they include skin cuts, needle sticks, workers bitten or scratched by infected animals, broken vials, leaks of contaminated waste, missing infected animals, dropped containers, defective seals on airtight containers, missing or lost shipments, and more. Exhibit 15. Thirty-six (36) accidents and lost shipments were reported between January and August 2007, which is nearly double the number reported during all of 2004. *Id.* In addition, as of October 2007, "[m]ore than two-dozen incidents were still under investigation." *Id.*

These mishaps substantially undercut the assertion in the new EA that "it is improbable laboratory staff would acquire accidental laboratory-acquired infection during the operation of the proposed BSL-3." Exhibit 6 at 51; *see* Exhibit 1 at ¶¶ 18-20. Similarly, the significant number of transportation-related incidents calls into question Defendants' claim that "[a]ccidents due to transportation of microorganisms are not expected to increase" due to operation of the proposed BSL-3 facility, particularly in light of the Livermore Lab anthrax release. Exhibit 6 at 57; *see* Exhibit 1 at ¶¶ 18-20; Exhibit 3 at ¶ 12. Biological shipments to the BSL-3 facility may currently be as high as 40 shipments in and 20 shipments out per month, or ten times the levels before the facility became operational, indicating a greater likelihood of another shipping mishap occurring. Exhibit 6 at 21. Although the final Revised EA contains a perfunctory discussion of recent laboratory-acquired infections, Defendants failed to take a "hard look" at the significant

new information regarding the safety and security of BSL-3 facilities, which requires supplementation of the Revised EA. *See* Exhibit 6 at 50-51.

iii. A report on the proliferation of high-containment biosafety laboratories

On October 4, 2007, the Government Accountability Office ("GAO") released a report documenting "a major proliferation of high-containment BSL-3 and BSL-4 labs" in the United States, which calls into question the need for the proposed BSL-3 facility at LLNL. Exhibit 17 at Highlights. The GAO report also stated that "[n]o single federal agency has the mission to track and determine the risk associated with the expansion of BSL-3 and BSL-4 labs in the United States, and no single federal agency knows how many such labs there are in the United States." *Id.* at 13. According to Keith Rhodes, Chief Technologist for the GAO, this lack of oversight "has caused particular concern among officials at the Federal Bureau of Investigation . . . because the laboratories themselves could become the source of agents that might be used in terrorist attacks." Exhibit 8.

In both the earlier EA and new EA, issued over five years apart, Defendants bolster their assertion that the proposed BSL-3 facility at LLNL is needed because "[c]ommercial or governmental BSL-3 facilities currently available are often heavily committed to other projects or tailored to work with specific types of microorganisms." Exhibit 5 at ii; Exhibit 6 at iii. While these statements, in themselves, are inadequately supported in either document, they are particularly dubious in light of the major expansion of BSL-3 laboratories over the past several years. *See* Exhibit 6 at 7-8; Exhibit 1 at ¶¶ 4-9. Although the GAO report is cited in the new EA for the proposition that "[t]here are currently over 1350 BSL-3 laboratory facilities in the United States at various non-DOE sites," there is no analysis of how the recent expansion in the number of these facilities may obviate the need for the proposed BSL-3 facility at Livermore Lab or how this proliferation may affect the terrorism analysis ordered by the Ninth Circuit. *See* Exhibit 6 at 61.

The major expansion of BSL-3 facilities in the United States over the past several years documented in the GAO report rises to the level of significant new circumstances warranting supplementation of the new EA.

iv. A hearing in Congress on the proliferation of high-containment biosafety laboratories

On October 4, 2007, the House Committee on Energy and Commerce's Subcommittee on Oversight and Investigations held a hearing entitled "Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States." In his opening statement, Chairman Stupak noted that "[t]he accidental or deliberate release of some of the biological agents handled at these labs could have catastrophic consequences." Exhibit 9. Chairman Stupak went on to question whether the unprecedented proliferation of these facilities is necessary. *Id.* At the hearing, federal officials "said that the expansion of the [biodefense] program over the last few years, coupled with a lack of training of lab workers and poor reporting of lab accidents, posed a potential threat to national security and public health." Exhibit 11.

This hearing, like the GAO report discussed above, raises substantial questions about the need for the proposed BSL-3 facility at Livermore Lab and the safety and security of these facilities. *See* Exhibit 1 at ¶¶ 4-21. These significant new circumstances and information require supplementation of the Revised EA.

v. A report assessing the biological weapons and bioterrorism threat

In December 2005, Milton Leitenberg, Senior Research Scholar at the Center for International and Security Studies at the University of Maryland, released a report entitled *Assessing the Biological Weapons and Bioterrorism Threat*. The report was prepared for the Strategic Studies Institute, a division of the U.S. Army War College. Exhibit 14. In his report, Leitenberg asserts that "the U.S. biodefense research program appears to be drifting into violation of Article 1 of the [Biological Weapons Convention ("BWC")]." *Id.* at 89-90.

This report is significant because, since Leitenberg established that there is no national-level oversight system to ensure compliance with the BWC, there is reason to question whether LLNL's management is capable of approving and authorizing the research to be conducted in the

proposed BSL-3 facility in strict compliance with the Convention, as stated in the new EA. *Id.* at 89; Exhibit 6 at 18; *see* Exhibit 1 at 11-16; Exhibit 3 at ¶¶ 20-24. This is particularly so because determining compliance with the BWC is notoriously difficult, as described above. *See* Exhibit 3 at ¶ 19. This significant new information necessitates supplementation of the new EA under applicable regulations.

While some of the new circumstances and events discussed above were mentioned in passing in the final version of the new EA, that document was not circulated for public comment. Accordingly, the public and other government agencies were denied the opportunity "to react to the effects of [the] proposed action at a meaningful time." *Marsh*, 490 U.S. at 371 (citing *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349-350, 109 S. Ct. 1835 (1989)). Under CEQ's regulations, "NEPA procedures must insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken." 40 C.F.R. § 1500.1(b) (1978). Therefore, Defendants have violated NEPA by failing to prepare and circulate a supplement to the new EA in response to significant new circumstances and information relevant to the environmental impacts of the proposed BSL-3 facility at Livermore Lab.

4) Failure to comply with applicable regulations

Plaintiffs are likely to prevail on their claim that Defendants violated applicable regulations implementing NEPA by issuing a FONSI for the proposed BSL-3 facility at Livermore Lab without public review and comment. Defendants' failure to comply with applicable federal regulations is arbitrary and capricious, an abuse of discretion, or contrary to law and constitutes a violation of the APA and NEPA.

Under the applicable regulations, Defendants were required to issue a proposed FONSI for the BSL-3 facility for public review and comment before making a final determination on the FONSI. Pursuant to the Department's Implementing Procedures under NEPA, "DOE shall issue a proposed FONSI for public review and comment before making a final determination on the FONSI if required [under the NEPA regulations promulgated by CEQ.]" 10 C.F.R. § 1021.322(d) (1996). Under CEQ's NEPA regulations, an agency shall make a FONSI available

for public review for 30 days before the agency makes its final determination whether to prepare an EIS and before the action may begin where "[t]he nature of the proposed action is one without precedent." 40 C.F.R. § 1501.4(e)(2) (1978).

Whether the nature of the proposed action "is 'without precedent' is largely a function of the definition one assigns to the term 'nature'." *Sabine River Authority v. U.S. Dep't of Interior*, 745 F. Supp. 388, 401 (D. Tex. 1990) (quoting 40 C.F.R. § 1501.4(e)(2)(ii)). In *Sabine River Authority*, the court reasoned that the common understanding of the word nature is "the essential character of something[.]" 745 F. Supp. at 401. Here, the essential character of the proposed action is the operation of a BSL-3 facility by DOE. Prior to commencing operation of the proposed BSL-3 facility at Livermore Lab, the Department had not previously operated any microbiological facilities above Biosafety Level 2 (BSL-2"). Exhibit 6 at iii.

Although DOE has previously operated BSL-2 facilities, there are important differences between BSL-2 and BSL-3. BSL-2 "is suitable for work involving agents of *moderate potential hazard to personnel and the environment*." *Id.* at A-4 (emphasis added). BSL-3 is applicable to "facilities in which work is done with infectious agents which may cause *serious or potentially lethal disease as a result of exposure by the inhalation route*." *Id.* at A-9 (emphasis added). As such, the bioagents to be contained in the proposed facility represent a much greater hazard to the public and the environment; namely, that of serious or lethal disease. Moreover, the indigenous or exotic agents that would be handled in the proposed facility have the potential for aerosol transmission. *Id.* This is particularly significant insofar as a loss of containment in the facility, which will aerosolize pathogenic material for small-animal testing, may have dire consequences on public health and safety and the environment that would not be applicable to a BSL-2 facility. Exhibit 3 at ¶ 6.

The *Sabine River Authority* court went on to note that, "even if the Court were to find that the 30-day comment period applied to the FONSI [at issue], the plaintiffs failed to identify any additional relevant information that they or any other party would have provided to the [agency]." 745 F. Supp. at 401. In the instant case, Plaintiffs and others would have provided significant information relevant to environmental concerns and bearing on the proposed action

and its impacts. *See* Exhibit 2 at ¶ 28. For instance, Plaintiffs would have provided further information about the Livermore Lab anthrax release and its implications regarding the terrorism analysis ordered by the Ninth Circuit. *See id.* Plaintiffs would also have provided information concerning the proliferation of BSL-3 facilities and the large number of accidents, security lapses, and shipping mishaps at such facilities since 2003. *Id.* Also, Plaintiffs would have provided information concerning the Leitenberg report. *Id.* Finally, depending on the timing of the public review and comment period, Plaintiffs would have provided information concerning the deliberate exposure of construction workers at Livermore Lab to the toxic metal beryllium, which implicates the safety and management protocols at LLNL. *Id.*

Accordingly, the proposed BSL-3 facility at LLNL is clearly without precedent, and Defendants violated applicable regulations by issuing the Revised FONSI without public review and comment.

III. THE BALANCE OF HARDSHIPS TIPS SHARPLY TOWARD PLAINTIFFS

The balance of hardships tips sharply in Plaintiffs' favor because the significant threat to the human environment posed by operation of the proposed BSL-3 facility under these circumstances far outweighs the resulting negligible delay in operations that a preliminary injunction would occasion. According to the Supreme Court, if environmental injury "is sufficiently likely, . . . the balance of harms will usually favor the issuance of an injunction to protect the environment." *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 545, 107 S. Ct. 1396 (1987).

Defendants propose to experiment with a number of deadly bioagents, including, but not limited to, the select agents *Bacillus anthracis* (anthrax), *Yersinia pestis* (plague), *Clostridium botulinum* (botulism), *Coccidioides immitis* (Valley Fever), *Brucella spp.* (Brucellosis), *Francisella tularensis* (tularemia), and *Coxiella burnetii* (Q Fever). Exhibit 6 at 18, 51. The proposed BSL-3 facility at Livermore Lab may also be used to handle small amounts of biotoxins and may receive genetically modified organisms. *Id.* at 18. In addition, the proposed facility may contain up to 50 liters of bioagents, a number of which could have offensive uses as bioweapons. *Id.* at iii, C-10. If released to the environment due to terrorist attack, earthquake,

fire, worker transmission, improper shipment, equipment malfunction, operator error, sabotage, or the like, these deadly pathogens would pose a grave danger of irreparable health impacts to an untold number of individuals. *See* Exhibit 2 at ¶ 10; Exhibit 3 at ¶¶ 7-17.

Moreover, Plaintiffs have suffered procedural injury as the result of Defendants' actions. *See* Exhibit 2 at ¶ 28. Defendants' obfuscation with regard to the August-September 2005 anthrax release effectively circumvented the public's ability to comment on an incident having important ramifications concerning the environmental impacts of the proposed facility. *See id.* at ¶¶ 25-26. Similarly, Plaintiffs also suffered procedural injury because Defendants failed to prepare and circulate a supplement to the EA in response to significant new circumstances and information. Under these circumstances, "the harm at stake is a harm to the environment, but the harm consists of the added risk to the environment that takes place when governmental decisionmakers make up their minds without having before them an analysis (with prior public comment) of the likely effects of their decision upon the environment." *Sierra Club v. Marsh*, 872 F.2d 497, 500-01 (1st Cir. 1989). In addition, Plaintiffs' suffered procedural injury because Defendants failed to prepare an EIS, which creates a risk that significant environmental impacts will be overlooked. Exhibit 2 at ¶ 47; *Davis v. Coleman*, 521 F.2d 661, 671 (9th Cir. 1975).

Any delay resulting from this requested preliminary injunction would be slight in comparison to the potentially catastrophic results of a release of deadly bioagents from the proposed BSL-3 facility. Defendants can advance no credible claim of prejudice from the negligible delay in operation of the proposed facility requested in this preliminary injunction. As noted above, it has been widely reported that there has been a major proliferation of BSL-3 facilities in recent years. Exhibit 1 at ¶ 4; Exhibit 17 at Highlights. Given that offsite BSL-3 facilities have been used in the past to support bioscience research at Livermore Lab, it is likely that such facilities could be engaged in the interim, particularly in light of the recent expansion in the number of these facilities. Exhibit 6 at 7-8; *see* Exhibit 1 at ¶ 10. Defendants' expected claim that there is a "national security" or other urgent need for the proposed facility is belied by Livermore Lab's trumpeted claims of "pioneering work on biological agent (bioagent) detection

and counter-terrorism technologies, and basic research understanding of emerging and re-emerging natural diseases" prior to operation of the proposed facility. Exhibit 6 at iii.

In light of the above, it is clear that the balance of hardships tips sharply in Plaintiffs' favor because the significant threat to the human environment posed by operation of the proposed facility in violation of NEPA far outweighs the resulting negligible delay in operations that may result from issuance of a preliminary injunction.

Therefore, Plaintiffs are entitled to interim injunctive relief. In addition to the factors discussed above, Plaintiffs have demonstrated the possibility of irreparable harm to the human environment from operation of the proposed BSL-3 facility at LLNL. *See* Exhibit 3 at ¶¶ 6-17. As the Supreme Court has explained, "[e]nvironmental injury, by its nature, can seldom be adequately remedied by money damages and is often permanent or at least of long duration, i.e., *irreparable*." *Amoco Prod. Co.*, 480 U.S. at 545 (emphasis added). Here, operation of the proposed BSL-3 facility at Livermore Lab threatens grave environmental injury. Moreover, as specified in detail above, Plaintiffs have raised serious questions about the legality of Defendants' actions in commencing operation of the proposed BSL-3 facility at Livermore Lab. These serious questions go to the merits of Plaintiffs' claims and also favor the issuance of a preliminary injunction in this instance.

IV. THE BOND AMOUNT SHOULD BE NOMINAL

Any bond required of Plaintiffs should be set—if at all—at a nominal amount in light of the fact that Plaintiffs are non-profit public benefit organizations and private citizens that have brought suit in order to ensure that Defendants comply with federal laws and regulations. The Court has "discretion to dispense with the security requirement, or to request mere nominal security, where requiring security would effectively deny access to judicial review." *California ex rel. Van De Kamp v. Tahoe Regional Planning Agency*, 766 F.2d 1319, 1325 (9th Cir. 1985) (citations omitted). Moreover, "special precautions to ensure access to the courts must be taken where Congress has provided for private enforcement of a statute," as it has done with NEPA. *Id.* at 1325-26 (citations omitted). As noted, Plaintiffs are non-profit organizations and concerned citizens with extremely modest economic resources. Exhibit 2 at ¶¶ 49-52.

V. CONCLUSION AND PRAYER FOR RELIEF

For the foregoing reasons, Plaintiffs have satisfied this Court's test for issuance of a preliminary injunction. Accordingly, this Court should grant Plaintiffs' Motion for Preliminary Injunction. The amount of bond, if any, should be nominal.

WHEREFORE, Plaintiffs respectfully request that this Court grant Plaintiffs the following relief:

a. Order Defendants to suspend operation of the BSL-3 facility at Livermore Lab pending a determination on the merits of this action.

b. Waive bond, or set a nominal bond.

c. Award Plaintiffs reasonable attorney and expert witness fees and expenses incurred in the litigation of this action.

Dated this 25th day of March, 2008

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

TRI-VALLEY CARES, MARYLIA KELLEY, JANIS KATE TURNER, and JEDIDJAH DE VRIES,

Plaintiffs,

vs.

UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION, and LAWRENCE LIVERMORE NATIONAL LABORATORY,

Defendants

Case No. 08-cv-01372-SBA

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

This matter comes before the Court on the motion for preliminary injunction filed by plaintiffs Tri-Valley CAREs, Marylia Kelley, Janis Kate Turner, and Jedidjah de Vries (collectively, "Plaintiffs") and the opposition thereto filed by defendants United States Department of Energy ("DOE" or "Department"), National Nuclear Security Administration

("NNSA"), and Lawrence Livermore National Laboratory ("Livermore Lab" or "LLNL") (collectively, "Defendants"). Having considered the arguments presented by the parties, the Court hereby GRANTS Plaintiffs' motion for preliminary injunction.

I. BACKGROUND

Defendants have commenced operation of a Biosafety Level 3 ("BSL-3") facility at Lawrence Livermore National Laboratory in Livermore, California. The proposed BSL-3 facility, which has an estimated operational design life of at least 30 years, is an approximately 1,500 square foot, permanent, prefabricated facility containing three individual BSL-3 laboratory rooms, one of which is capable of handling rodents. Exhibit 6 at iii. BSL-3 facilities are suitable for work with indigenous or exotic biological agents ("bioagents") that may cause serious or potentially lethal disease as a result of exposure by the inhalation route. *Id.* at A-9.

The proposed BSL-3 facility at Livermore Lab may contain up to 50 liters of bioagents, and many of these could have offensive uses as bioweapons. *Id.* at iii, C-10. In addition, the proposed facility may also be used to handle biotoxins and genetically engineered microorganisms. *Id.* at 18. Up to 100 rodents—mice, rats, and guinea pigs—would be used at any one time in the BSL-3 laboratory designated for rodent handling. *Id.* at 16. Rodents would be exposed to pathogenic material in a biological safety cabinet through inhalation via a device known as a collision nebulizer, which creates aerosol particles of known size (depending upon the specific nozzle used) to which rodents would be exposed through a nose-piece. *Id.*

As a result of prior litigation initiated by Tri-Valley CAREs, et al. challenging, inter alia, the adequacy of the Environmental Assessment ("EA") and Finding of No Significant Impact ("FONSI") for the proposed facility, the United States Court of Appeals for the Ninth Circuit ordered "DOE to consider whether the threat of terrorist activity [at the proposed BSL-3 facility

at Livermore Lab] necessitates the preparation of an Environmental Impact Statement [("EIS")]." *Tri-Valley CAREs v. Department of Energy*, No. 04-17232, mem. op. at 4 (9th Cir. 2006). Following the Ninth Circuit's decision, the Department issued interim guidance on how to address intentional destructive acts in NEPA documents. *See* Exhibit 13 at 1.

In response to the Ninth Circuit's ruling and DOE's guidance, NNSA revised the EA for the proposed facility to consider the potential impacts of terrorist activity. Exhibit 6 at ii. NNSA then sought public comment on the new EA during a 30-day comment period beginning April 11, 2007, and ending May 11, 2007. *Id.* at C-1. On January 25, 2008, Defendants issued a final EA and FONSI for the proposed BSL-3 facility at Livermore Lab and immediately commenced operations therein.

II. LEGAL STANDARD

A plaintiff is entitled to a preliminary injunction if she demonstrates "*either* '(1) a likelihood of success on the merits and the possibility of irreparable injury; or (2) that serious questions going to the merits were raised and the balance of hardships tips sharply in its favor.'" *Nelson v. NASA*, 2008 U.S. App. LEXIS 498, at *9, 512 F.3d 1132 (9th Cir. 2008) (emphasis added) (quoting *Walczak v. EPL Prolong, Inc.*, 198 F.3d 725, 731 (9th Cir. 1999)). The two prongs are not separate tests, as such, but "rather 'extremes of a single continuum,' so 'the greater the relative hardship to [the party seeking the preliminary injunction], the less probability of success must be shown.'" *Nelson*, 2008 U.S. App. LEXIS 498, at *9 (quoting *Walczak*, 198 F.3d at 731).

The Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A) (1966), governs the Court's review of Defendants' actions, conclusions, and findings of fact, which must be set aside "if they are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with

law.'" *Ocean Advocates v, United States Army Corps of Eng'rs*, 402 F.3d 846, 858 (9th Cir. 2005) (quoting 5 U.S.C. § 706(2)(A)). Judicial review under the arbitrary and capricious standard is "searching and careful," but a reviewing court is "not empowered to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, 91 S. Ct. 814 (1971), *overruled on other grounds by Califano v. Sanders*, 430 U.S. 99, 105, 97 S. Ct. 980 (1977). The Court "must consider whether the decision was based on a consideration of relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park, Inc.*, 401 U.S. at 416; *see Ariz. Cattle Growers' Ass'n v. United States Fish & Wildlife Serv.*, 273 F.3d 1229, 1236 (9th Cir. 2001) (citations omitted) (A reviewing court "must determine whether the agency articulated a rational connection between the facts found and the choice made."). Reviewing courts "must not 'rubber-stamp . . . administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute.'" *Ariz. Cattle Growers' Ass'n*, 273 F.3d at 1236 (citing *NLRB v. Brown*, 380 U.S. 278, 291-92, 85 S. Ct. 980 (1965)).

The National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321 *et seq*. (1975), "imposes only procedural requirements on federal agencies with a particular focus on requiring agencies to undertake analyses of the environmental impact of their proposals and actions." *Department of Transportation v. Public Citizen*, 541 U.S. 752, 756-57, 124 S. Ct. 2204 (2004) (citing *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349-50, 109 S. Ct. 1835 (1989)). Pursuant to NEPA, agencies are required to "take a 'hard look' at the environmental consequences before taking a major action." *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 97, 103 S. Ct. 2246 (1983) (quoting *Kleppe v. Sierra Club*, 427 U.S. 390, 410, n. 21, 96 S. Ct. 2718 (1976)).

III. ANALYSIS

Plaintiffs' motion for preliminary injunction is made on the grounds that interim injunctive relief is warranted in this case under either of the two applicable standards because Plaintiffs can show both that (1) they are likely to prevail on the merits, and (2) the balance of hardships tips sharply toward Plaintiffs.

a. Plaintiffs are likely to prevail on the merits

Plaintiffs plead four counts against Defendants in their complaint: (1) failure to prepare an adequate EA and FONSI, (2) failure to prepare an EIS, (3) failure to supplement, and (4) failure to comply with applicable regulations. The Court finds that Plaintiffs are likely to prevail on the merits of their claims against Defendants.

1. Failure to prepare an adequate EA and FONSI

Plaintiffs allege that, in violation of NEPA, Defendants failed to take a "hard look" at whether the threat of terrorist activity at the proposed BSL-3 facility necessitates the preparation of an EIS. According to Plaintiffs, the terrorism analysis is inadequate in the following respects, among others: (1) the terrorism analysis is based on an inapplicable and flawed accident scenario, and (2) the terrorism analysis is unreasonable and unsupported.

In analyzing the threat of terrorist activity at the proposed facility, Defendants rely, in part, on the bounding analysis contained in the original EA, which allegedly compensates for analytical uncertainty by using a conservative approach to overestimate potential impacts. Exhibit 6 at 59. This bounding analysis involves a centrifuge accident leading to a release of *Coxiella burnetii* (Q Fever). *Id.* at 53-55. However, as DOE itself acknowledged in a 2006 memorandum, applying an analysis of accidents to an analysis of the potential consequences of acts of sabotage or terrorism "may not be adequate for all situations, because *accident scenarios*

may not fully encompass potential threats posed by intentional destructive acts." Exhibit 13 at 2 (emphasis added). In this case, the bounding analysis used by Defendants does not fully encompass the terrorist threat because it fails to account for a terrorist attack resulting in breach or rupture of the proposed facility's walls.

Moreover, Defendants unreasonably assume that diagnostic and medical treatment will be available in the event of a terrorist attack, even though Defendants admit that the bioagents to be handled in the proposed facility "can be extremely difficult to detect and some may not cause illness immediately." Exhibit 6 at 60. Defendants also unreasonably assume that the proposed facility does not represent an attractive target for terrorists because the pathogenic material to be contained therein is readily obtainable from the environment. *See id.* This assertion overlooks the fact that the proposed facility will contain large quantities of bioagents of known virulence, including genetically engineered microorganisms that could not be obtained from the environment. *Id.* at 7, C-10, Exhibit 3 at ¶¶ 14-15. Finally, Defendants fail to analyze the direct and indirect effects associated with cleanup activities following a terrorist attack at the proposed facility, which could be substantial.

In light of the above, the Court finds that Plaintiffs are likely to prevail on the merits of their claim that Defendants have violated NEPA by failing to take a "hard look" at whether the threat of terrorist activity at the proposed BSL-3 facility necessitates the preparation of an EIS.

2. Failure to prepare an EIS

Plaintiffs also allege that Defendants violated NEPA by failing to prepare an EIS for the proposed BSL-3 facility at Livermore Lab. An EIS must be prepared for "major Federal actions significantly affecting the quality of the human environment . . . ." 42 U.S.C. § 4332(2)(C). If substantial questions are raised as to whether a project *may* cause significant degradation of some

human environmental factor, an EIS must be prepared. *Ocean Advocates*, 402 F.3d at 864-65 (emphasis in original) (quoting *Idaho Sporting Cong. v. Thomas*, 137 F.3d 1146, 1149 (9th Cir. 1998) (citation omitted)). A plaintiff is not required to show that significant effects will in fact occur; it is sufficient to raise substantial questions whether a project *may* have a significant effect. *Ocean Advocates*, 402 F.3d at 865 (quoting *Greenpeace Action v. Franklin*, 14 F.3d 1324, 1332 (9th Cir. 1992)).

As used in NEPA, significance "requires considerations of both context and intensity." 40 C.F.R. § 1508.27 (1979). Context "means that the significance of an action must be analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality[,]" while intensity "refers to the severity of impact." *Id.* at § 1508.27(a-b). The following factors, among others, should be considered in evaluating intensity:

> 1. Impacts that may be both beneficial and adverse. A significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial.
> 2. The degree to which the proposed action affects public health of safety.
> . . .
> 4. The degree to which the effects on the quality of the human environment are likely to he highly controversial.
> 5. The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.
> . . .
> 10. Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.

Id. at § 1508.27(b).

Regarding context, operation of the proposed facility may have significant impacts at the local, regional, and national levels. Most obviously, a release of pathogenic material from the proposed BSL-3 facility could result in the exposure of a large number of individuals at LLNL and the surrounding communities. *See* Exhibit 2 at ¶¶ 11-13; Exhibit 3 at ¶¶ 10-11,17. Given Livermore Lab's close proximity to Interstate 580 and the San Francisco Bay Area, such a

release could also have significant regional impacts. *See* Exhibit 3 at ¶ 13. Finally, as evidenced by the significant disruptions occasioned by the anthrax mailings in 2001, an accidental release, a terrorist attack on the proposed facility, or the theft and subsequent release of pathogenic material from the facility could have significant impacts nationally as well.

The proposed BSL-3 facility at Livermore Lab may significantly affect the quality of the human environment in the following respects, among others: (1) operation of the proposed facility may affect public health and safety; (2) the possible effects on the quality of the human environment from operation of the proposed facility are highly controversial; (3) the possible effects on the human environment from operation of the proposed facility are highly uncertain and involve unique or unknown risks; and (4) the proposed action, operation of a BSL-3 facility at Livermore Lab for biodefense purposes, threatens a violation of the Biological Weapons Convention, to which the United States is a State Party.

First, operation of the proposed BSL-3 facility at LLNL, including the inadequately studied risks of terrorist attack, accidents, earthquake, and fire, has the potential to cause significant impacts to public health and safety. *See* Exhibit 2 at ¶ 10; Exhibit 3 at ¶¶ 7-17. Second, the possible effects on the quality of the human environment from operation of the proposed facility are highly controversial. A proposed action "is highly controversial when there is 'a substantial dispute [about] the size, nature, or effect of the major Federal action rather than the existence of opposition to a use.'" *Anderson v. Evans*, 371 F.3d 475, 489 (9th Cir. 2004) (quoting *Blue Mts. Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1212 (9th Cir. 1998) (citation omitted)). Here, there are substantial disputes regarding the need for the proposed facility, the consequences of an accidental or deliberate release of pathogenic material from the

facility, as well as the proposed action's compliance with the Biological Weapons Convention. *See* Exhibit 1 at ¶¶ 4-21; Exhibit 2 at ¶¶ 36-40; Exhibit 3 at ¶¶ 7-24.

Third, the possible effects on the human environment from operation of the proposed BSL-3 facility are highly uncertain and involve unique or unknown risks. An agency "must generally prepare an EIS if the environmental effects of a proposed agency action are highly uncertain." *National Parks & Conservation Ass'n v. Babbitt*, 241 F.3d 722, 731-32 (9th Cir. 2001) (citing *Blue Mts. Biodiversity Project*, 161 F.3d at 1212). Preparation of an EIS "is mandated where uncertainty may be resolved by further collection of data," or "where the collection of such data may prevent 'speculation on potential . . . effects. The purpose of an EIS is to obviate the need for speculation by insuring that available data are gathered and analyzed prior to the implementation of the proposed action.'" *National Parks & Conservation Ass'n*, 241 F.3d at 732 (citing *Blue Mts. Biodiversity Project*, 161 F.3d at 1213-14; quoting *Sierra Club v. United States Forest Service*, 843 F.2d 1190, 1194 (9th Cir. 1988)).

In this case, the possible effects on the human environment from operation of the proposed facility are highly uncertain because there is no precedent for a release of pathogenic material from such a facility in the United States. Exhibit 6 at 52. Although Defendants attempt to use this historical evidence to justify their failure to consider the consequences of such a release, the Ninth Circuit has clearly indicated that incidents of this nature are not so remote and highly speculative as to be beyond NEPA's requirements. *See Tri-Valley CAREs*, No. 04-17232, mem. op. at 4; *San Luis Obispo Mothers for Peace v. NRC*, 449 F.3d 1016, 1030 (9th Cir. 2006). Moreover, on April 2, 1979, an accidental anthrax release occurred at a military microbiology facility at Sverdlovsk, in the former Soviet Union. Exhibit 3 at ¶¶ 7-9. Over 100 people died as a result of this incident, which was caused by operator error in removing a High Efficiency

Particulate Air-Purifying ("HEPA") filter and not replacing it. *Id.* at ¶ 8. Furthermore, since the proposed BSL-3 facility will handle bioagents that could have offensive uses as bioweapons, and potentially genetically modified versions thereof, the proposed action involves unique or unknown risks to the human environment. Exhibit 6 at ii, 18; *see* Exhibit 3 at ¶ 15.

Finally, the proposed action, operation of a BSL-3 facility at LLNL for biodefense purposes, threatens a violation of the Biological Weapons Convention ("BWC"), to which the United States is a State Party. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction ("BWC"), Mar. 26, 1975, 26 U.S.T. 583, 1015 U.N.T.S. 163. Pursuant to Article I of the BWC, each State Party "undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain . . . microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes[.]" *Id.* at art. I.

Given that the proposed BSL-3 facility may contain up to 50 liters (or 25,000 vials) of pathogenic material and that research to be conducted therein may involve aerosolization and genetic manipulation of bioagents and biotoxins, there are substantial questions as to whether the proposed action may transgress the BWC. Exhibit 6 at 7, C-10; *see* Exhibit 1 at ¶¶ 11-16; Exhibit 2 at ¶ 38; Exhibit 3 at ¶¶ 18-24. Moreover, although Defendants claim that Livermore Lab's management will ensure compliance with the Convention, there is no indication as to what expertise LLNL's management brings to bear to this matter or what criteria would guide these determinations. *See* Exhibit 6 at 18. Since compliance with the BWC is a difficult issue even for experts in the field, these words ring hollow, particularly in light of Defendants' failure to provide any information as to how compliance would be instituted after public comments

explicitly raised such concerns during the public comment periods for both EAs. *See* Exhibit 3 at ¶ 19; Exhibit 5 at C-7-8; Exhibit 6 at C-10-11.

Even though the research to be conducted in the proposed BSL-3 facility at LLNL would be "directed to developing technologies and systems to improve national defense against, and mitigate the consequences of . . . terrorist attacks[,]" Defendants cannot use the presupposed benefits of this research to override the significant effects that may result from operation of the proposed facility and which necessitate the preparation of an EIS. Exhibit 6 at 56-57. As specified above, "[a] significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial." 40 C.F.R. § 1508.27(b)(1).

Because Plaintiffs have raised substantial questions whether the proposed BSL-3 facility at Livermore Lab may have significant effects on the human environment, the Court finds that Plaintiffs are likely to prevail on the merits of their claim that Defendants violated NEPA by failing to prepare an EIS for the proposed facility.

3. Failure to supplement

In addition, the Court finds that Plaintiffs are likely to prevail on the merits of their claim that Defendants violated applicable regulations implementing NEPA by failing to prepare a supplement to the new EA in response to significant new circumstances and information relevant to the environmental impacts of the proposed BSL-3 facility at Livermore Lab. Moreover, there are indications that Defendants deliberately withheld some of this information until after the public comment period for the new EA had ended.

Federal agencies have "a continuing duty to gather and evaluate new information relevant to the environmental impact of [the agencies'] actions." *Warm Springs Dam Task Force v. Gribble*, 621 F.2d 1017, 1024 (9th Cir. 1980) (citing 42 U.S.C. § 4332(2)(A-B) (1975)); *Essex*

County Preservation Ass'n v. Campbell, 536 F.2d 956, 960-61 (1st Cir. 1976); *Society for Animal Rights, Inc. v. Schlesinger*, 512 F.2d 915, 917-18 (D.C.Cir.1975)). Pursuant to the Department's regulations implementing NEPA, "DOE shall prepare a supplemental EIS if there are . . . significant new circumstances or information relevant to environmental concerns," as discussed in the NEPA regulations promulgated by CEQ. 10 C.F.R. § 1021.314(a) (1992). Under CEQ's regulations, agencies shall prepare supplements to either draft or final EISs if "[t]here are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts." 40 C.F.R. § 1509(c)(1)(ii) (1978). The Supreme Court has interpreted NEPA, in light of this regulation, as requiring an agency to take a "hard look" at new circumstances and information to determine whether supplementation may be required. *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 72-73, 124 S. Ct. 2373 (2004) (citing *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 378-85, 109 S. Ct. 1851 (1989)).

Although the instant action concerns supplementation of an EA, the standard for supplementing an EA is the same as for an EIS. *Idaho Sporting Congress, Inc. v. Alexander*, 222 F.3d 562, 566 n.2 (9th Cir. 2000) (citations omitted); *see Price Rd. Neighborhood Ass'n v. United States DOT*, 113 F.3d 1505, 1509-10 (9th Cir. 1997); *Friends of the Bow v. Thompson*, 124 F.3d 1210, 1218 n.3 (10th Cir. 1997) (citations omitted); *Clinch Coalition v. Damon*, 316 F. Supp. 2d 364, 376 (D. Va. 2004) (citations omitted).

The following significant new circumstances and information relevant to environmental concerns and bearing on the proposed action and its impacts require supplementation of the new EA for the proposed BSL-3 facility at LLNL: (1) the Livermore Lab anthrax release in August-September 2005; (2) information regarding the safety and security of BSL-3 facilities; (3) a

report on the proliferation of high-containment biosafety laboratories; (4) a hearing in Congress on the proliferation of high-containment biosafety laboratories; and (5) a report assessing the biological weapons and bioterrorism threat. In particular, the Court notes that the anthrax release is directly relevant to the terrorism analysis ordered by the Ninth Circuit, and the recent proliferation of BSL-3 facilities calls into question the need for the proposed facility.

While some of these significant new circumstances and information were mentioned in passing in the final version of the new EA, that document was not circulated for public comment. Accordingly, the public and other government agencies were denied the opportunity "to react to the effects of [the] proposed action at a meaningful time." *Marsh*, 490 U.S. at 371 (citing *Methow Valley Citizens Council*, 490 U.S. at 349-350). Under CEQ's regulations, "NEPA procedures must insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken." 40 C.F.R. § 1500.1(b) (1978).

Therefore, the Court also finds that Plaintiffs are likely to prevail on the merits of their claim that Defendants violated NEPA by failing to prepare and circulate a supplement to the new EA in response to significant new circumstances and information relevant to the environmental impacts of the proposed BSL-3 facility at Livermore Lab.

4. Failure to comply with applicable regulations

Finally, the Court finds that Plaintiffs are likely to prevail on the merits of their claim that Defendants violated applicable regulations implementing NEPA by issuing a FONSI for the proposed BSL-3 facility at Livermore Lab without public review and comment. Pursuant to the Department's Implementing Procedures under NEPA, "DOE shall issue a proposed FONSI for public review and comment before making a final determination on the FONSI if required [under the NEPA regulations promulgated by CEQ.]" 10 C.F.R. § 1021.322(d) (1996). Under CEQ's

NEPA regulations, an agency shall make a FONSI available for public review for 30 days before the agency makes its final determination whether to prepare an EIS and before the action may begin where "[t]he nature of the proposed action is one without precedent." 40 C.F.R. § 1501.4(e)(2) (1978).

Whether the nature of the proposed action "is 'without precedent' is largely a function of the definition one assigns to the term 'nature'." *Sabine River Authority v. U.S. Dep't of Interior*, 745 F. Supp. 388, 401 (D. Tex. 1990) (quoting 40 C.F.R. § 1501.4(e)(2)(ii)). In *Sabine River Authority*, the court reasoned that the common understanding of the word nature is "the essential character of something[.]" 745 F. Supp. at 401. Here, the essential character of the proposed action is the operation of a BSL-3 facility by DOE. Prior to commencing operation of the proposed BSL-3 facility at Livermore Lab, the Department had not previously operated any microbiological facilities above Biosafety Level 2 (BSL-2"). Exhibit 6 at iii.

The *Sabine River Authority* court went on to note that, "even if the Court were to find that the 30-day comment period applied to the FONSI [at issue], the plaintiffs failed to identify any additional relevant information that they or any other party would have provided to the [agency]." 745 F. Supp. at 401. In the instant case, Plaintiffs and others would have provided significant information relevant to environmental concerns and bearing on the proposed action and its impacts, including information about the Livermore Lab anthrax release, the proliferation of BSL-3 facilities, and the large number of mishaps at these facilities in recent years. *See* Exhibit 2 at ¶ 28.

Accordingly, the proposed BSL-3 facility at LLNL is without precedent, and the Court also finds that Plaintiffs are likely to prevail on the merits of their claim that Defendants violated

applicable regulations implementing NEPA by issuing the Revised FONSI without public review and comment.

b. The balance of hardships tips sharply toward Plaintiffs

The Court finds that the balance of hardships tips sharply in Plaintiffs' favor because the significant threat to the human environment posed by operation of the proposed BSL-3 facility under these circumstances far outweighs the resulting negligible delay in operations that a preliminary injunction would occasion. According to the Supreme Court, if environmental injury "is sufficiently likely, . . . the balance of harms will usually favor the issuance of an injunction to protect the environment." *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 545, 107 S. Ct. 1396 (1987).

Defendants propose to experiment with a number of deadly bioagents, including, but not limited to, the select agents *Bacillus anthracis* (anthrax), *Yersinia pestis* (plague), *Clostridium botulinum* (botulism), *Coccidioides immitis* (Valley Fever), *Brucella spp.* (Brucellosis), *Francisella tularensis* (tularemia), and *Coxiella burnetii* (Q Fever). Exhibit 6 at 18, 51. The proposed BSL-3 facility at Livermore Lab may also be used to handle small amounts of biotoxins and may receive genetically engineered microorganisms. *Id.* at 18. In addition, the proposed facility may contain up to 50 liters of bioagents, a number of which could have offensive uses as bioweapons. *Id.* at iii, C-10. If released to the environment due to terrorist attack, earthquake, fire, worker transmission, improper shipment, equipment malfunction, operator error, sabotage, or the like, these deadly pathogens would pose a grave danger of irreparable health impacts to an untold number of individuals. *See* Exhibit 2 at ¶ 10; Exhibit 3 at ¶¶ 7-17.

Moreover, Plaintiffs have suffered procedural injury as the result of Defendants' actions. *See* Exhibit 2 at ¶ 28. Defendants' obfuscation with regard to the August-September 2005 anthrax release effectively circumvented the public's ability to comment on an incident having important ramifications concerning the environmental impacts of the proposed facility. *See id.* at ¶¶ 25-26. Similarly, Plaintiffs also suffered procedural injury because Defendants failed to prepare and circulate a supplement to the EA in response to significant new circumstances and information. Under these circumstances, "the harm at stake is a harm to the environment, but the harm consists of the added risk to the environment that takes place when governmental decisionmakers make up their minds without having before them an analysis (with prior public comment) of the likely effects of their decision upon the environment." *Sierra Club v. Marsh*, 872 F.2d 497, 500-01 (1st Cir. 1989). In addition, Plaintiffs' suffered procedural injury because Defendants failed to prepare an EIS, which creates a risk that significant environmental impacts will be overlooked. Exhibit 2 at ¶ 47; *Davis v. Coleman*, 521 F.2d 661, 671 (9th Cir. 1975).

Any delay resulting from this requested preliminary injunction would be slight in comparison to the potentially catastrophic results of a release of pathogenic bioagents from the proposed BSL-3 facility. Defendants can advance no credible claim of prejudice from the minor delay in operation of the proposed facility requested in Plaintiffs' motion for preliminary injunction. Given that offsite BSL-3 facilities have been used in the past to support bioscience research at Livermore Lab, it is likely that such facilities could be engaged in the interim, particularly in light of the recent proliferation of these facilities. Exhibit 6 at 7-8; *see* Exhibit 1 at ¶¶ 4, 10; Exhibit 17 at Highlights. Defendants' expected claim that there is a "national security" or other urgent need for the proposed facility is belied by Livermore Lab's trumpeted claims of "pioneering work on biological agent (bioagent) detection and counter-terrorism

technologies, and basic research understanding of emerging and re-emerging natural diseases" prior to operation of the proposed facility. Exhibit 6 at iii.

In light of the above, the Court finds that the balance of hardships tips sharply in Plaintiffs' favor because the significant threat to the human environment posed by operation of the proposed facility in violation of NEPA far outweighs the resulting negligible delay in operations that may result from issuance of a preliminary injunction.

Therefore, Plaintiffs are entitled to interim injunctive relief. In addition to the factors discussed above, Plaintiffs have demonstrated the possibility of irreparable harm to the human environment from operation of the proposed BSL-3 facility at LLNL. *See* Exhibit 3 at ¶¶ 6-17. As the Supreme Court has explained, "[e]nvironmental injury, by its nature, can seldom be adequately remedied by money damages and is often permanent or at least of long duration, i.e., *irreparable*." *Amoco Prod. Co.*, 480 U.S. at 545 (emphasis added). Here, operation of the proposed BSL-3 facility at Livermore Lab threatens grave environmental injury. Moreover, as specified in detail above, Plaintiffs have raised serious questions about the legality of Defendants' actions in commencing operation of the proposed BSL-3 facility at Livermore Lab. These serious questions go to the merits of Plaintiffs' claims and also favor the issuance of a preliminary injunction in this instance.

c. The bond amount should be nominal

Finally, the Court finds that the bond required of Plaintiffs should be set at a nominal amount in light of the fact that Plaintiffs are non-profit public benefit organizations and private citizens that have brought suit in order to ensure that Defendants comply with federal laws and regulations. The Court has "discretion to dispense with the security requirement, or to request mere nominal security, where requiring security would effectively deny access to judicial

review." *California ex rel. Van De Kamp v. Tahoe Regional Planning Agency*, 766 F.2d 1319, 1325 (9th Cir. 1985) (citations omitted). Moreover, "special precautions to ensure access to the courts must be taken where Congress has provided for private enforcement of a statute," as it has done with NEPA. *Id.* at 1325-26 (citations omitted). As noted, Plaintiffs are non-profit organizations and concerned citizens with extremely modest economic resources. Exhibit 2 at ¶¶ 49-52.

IV. CONCLUSION

GOOD CAUSE APPEARING from the Plaintiffs' motion for preliminary injunction and supporting memorandum of points and authorities, the declarations of Edward Hammond, Marylia Kelley, and Mark Wheelis, Ph.D., and the Court having considered the opposition submitted thereto by Defendants,

IT IS HEREBY ORDERED that Defendants, their agents, officers, representatives, servants and employees, and all persons acting under, in concert with, or for them, are enjoined from operating the proposed Biosafety Level 3 ("BSL-3") facility at Lawrence Livermore National Laboratory that is the subject of this action, pursuant to administrative approvals that are challenged in this proceeding, pending the Court's review and disposition of this matter.

BOND on this preliminary injunction is hereby fixed at _____.

Dated: _____, 2008

_____
Hon. Saundra B. Armstrong
United States District Judge

EXHIBIT 1

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

TRI-VALLEY CARES, MARYLIA KELLEY, JANIS KATE TURNER, and JEDIDJAH DE VRIES, Plaintiffs, vs. UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION, and LAWRENCE LIVERMORE NATIONAL LABORATORY, Defendants	Case No.: DECLARATION OF EDWARD HAMMOND IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

1. I am Director of the Sunshine Project, whose primary place of business is P.O. Box 41987, Austin, Texas 78704. The Sunshine Project is a 501(c)3 non-profit, non-governmental organization that works to prevent the development and use of biological weapons, avert the use of biotechnology for hostile purposes, and to uphold and strengthen international agreements prohibiting biological warfare.

2. Since 1995, I have worked as Director and Program Officer of non-profit organizations specializing in international policy issues related to biotechnology, participating in that capacity at intergovernmental meetings of the Biological and Toxin Weapons Convention, the Chemical Weapons Convention, the World Health Assembly of the World Health Organization, the Commission on Plant Genetic Resources for Food and Agriculture, the International Plant Protection Convention of the United Nations Food and Agriculture Organization, the Convention on Biological Diversity and its Cartagena Biosafety Protocol of the United Nations Environment Program, and policy and legal development bodies of the Association of South East Asian Nations and the Organization of African Unity.

3. In my capacity as Director of the Sunshine Project, it has been my responsibility to advocate for a strengthened and verifiable Biological and Toxin Weapons Convention (BTWC) and to monitor U.S.-based research on biological weapons agents and delivery technologies for the purpose of identifying any aberration from strict compliance by the United States with its commitments as a state party to the BTWC. Because many of the technologies and knowledge generated in the course of biological defense research have applicability to offensive weapons programs (i.e. are "dual-use"), monitoring of biological defense research is an important element of my work. Through monitoring U.S. biodefense programs, I have gained detailed knowledge of the functions and capabilities of biological defense research facilities operated by the U.S. government and by educational institutions and private entities. Because of the impact of new federal appropriations made following September 11, 2001, and the subsequent anthrax mailings, for the past several years, I have dedicated a large amount of time identifying and tracking the numerous new proposals for construction of biological defense research facilities. Among the venues before which I have appeared, I provided written and spoken expert testimony on

biological defense facilities and programs for the U.S. Congress, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce on October 4, 2007.

4. There has been a large and unsafe expansion of U.S. laboratories handling biological weapons agents since 2002. This expansion poses significant risks to the public through accidents and incidents of domestic source criminality (bioterrorism). It should be noted that the still-unsolved 2001 anthrax mailings are widely believed to have been perpetrated and/or assisted by a current or former U.S. biological defense worker.

5. The unprecedented expansion of biological weapons agent research has been conducted without a national laboratory needs assessment and appears to far exceed that which is prudent and necessary for our national needs. Alarmingly, there is no comprehensive government source of information available on where these laboratories are and are being built. Inadequate transparency exacerbates risks to the public and threatens international confidence in the objectives and activities of this U.S. research, damaging prospects of improving global biosecurity. This is also highlighted in the testimony of the U.S. Government Accountability Office, "High-Containment Biosafety Laboratories, Preliminary Observations of the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States," October 4, 2007 (GAO-08-108T).

6. Because no one knows how many existing BSL-3 laboratories there are in the U.S. and where they are all located, as well as gaps in public information on new federally-funded facilities to study biological weapons agents, it is not possible to calculate the total increase in BSL-3 capacity; however, it is plainly very large. The National Institutes of Health ("NIH") has funded 13 new Regional Biocontainment Laboratories, plus its own new facilities and others constructed by government agencies, including the Departments of Defense, Energy, and Agriculture. In addition, many universities and other institutes have constructed BSL-3 and BSL-4 laboratories with their own funds, seeking to use the existence of the facility as leverage for federal research funding.

7. It is important to note that while BSL-4 labs are most frequently in the public eye because they are purpose-built to handle the most dangerous biological agents, BSL-3 laboratories handle

diseases that are also extremely dangerous to both researchers and the public and which pose potentially catastrophic risks if released by accident or malfeasance. These include diseases capable of transmission through the general population, including pandemic strains of influenza such as 1918 "Spanish" Flu, SARS coronavirus, and plague (*Yersinia pestis*), as well as animal and/or human threats such as Foot and Mouth Disease and H5N1 "Bird Flu" strains.

8. Although the United States clearly needs a biological defense program, in the past six years laboratory expansion has gone far beyond what is prudent and necessary, and without an adequate regulatory framework. According to the most recent statements by the Centers for Disease Control and Prevention ("CDC"), there are now approximately 400 facilities and 15,000 people in the United States handling biological weapons agents. The proposed upgrades and new facilities for biological defense research will facilitate access to biological weapons agents and knowledge of their use for a greatly increased number of individuals. Examples of these skills include growing and purifying large quantities of highly infectious agent in containment, agent aerosolization (in, for example, challenge tests), and genetic alteration of weapons agents. It is plain to see that our own scores of laboratories that study biological weapons agents represent the easiest avenue by which a would-be bioterrorist could obtain the materials and knowledge necessary to commit crime in the United States.

9. In light of the above, a reduction in the number of facilities and persons handling biological weapons agents is a highly desirable step for both safety and security. This could include cancellation or conversion of some planned and under construction facilities and rerouting of some appropriations toward basic research and public health, in order to help address problems that Americans most frequently face, which are not at all typically caused by biological weapons agents.

10. The Department of Energy ("DOE" or "Department") has developed biological weapons agent detection equipment and decontamination equipment. However, this work has little need for its own BSL-3 facilities. Many of the agents considered to be a bioterrorism threat can effectively be simulated by benign organisms or simulant organisms that pose much lower levels of risk to people, animals, and the environment. The U.S. Army maintains facilities (at Dugway

Proving Ground in Utah and elsewhere) for testing detection and decontamination equipment when the need to do so arises. Moreover, the recent proliferation of BSL-3 laboratories suggests there is no merit in DOE's assertion that there is a lack of capacity at offsite commercial or governmental BSL-3 facilities to perform such research on the Department's behalf.

11. The proposed BSL-3 facility at Lawrence Livermore National Laboratory ("LLNL" or "Livermore Lab") will work with a large number of, by DOE's own admission, pathogens "historically used as biological weapons." These are euphemistically termed "select agents" under 42 C.F.R. § 73 (2005).

12. The final Revised Environmental Assessment ("EA") for the proposed BSL-3 facility at LLNL indicates that laboratory cultures of biological weapons agents may be as large as 1 liter of cultured microorganisms (maximum cell density of about 10^8 cells per ml) in each of the laboratories within the BSL-3 facility. Final Revised EA at 20. It is extremely difficult to envisage a legitimate prophylactic use for this quantity of pathogen. For example, *Coxiella burnetii*, the causative agent of Q fever, is among the agents Livermore Lab intends to study at the proposed BSL-3 facility. The human inhalation infectious dose for *Coxiella burnetii* is considered to be 10 organisms. If LLNL produced cultures of *Coxiella burnetii* in one liter quantities, with an assumed saturated solution of 108 organisms per milliliter, the 1 liter culture of *Coxiella burnetii* would have enough organisms to cause 10 billion human infections.

13. Production of gram or sub-gram quantities of any pathogen is sufficient for defensive biological weapons work, particularly for the development of biological weapons agent detection equipment and decontamination equipment.

14. The EA for the proposed BSL-3 facility at Livermore Lab indicates that aerosol challenge tests on rodents are planned for the facility. In order for this type of testing to yield useful information for a biological defense program, the challenge agent (e.g., *Coxiella burnetii*) must be prepared in a manner to simulate warfare conditions and technologies used by potential enemies. Such research poses greater than normal health risks to laboratory workers and the

surrounding communities because it is designed to render the agents more infectious and pervasive in an open environment.

15. The EA mentions a number of organisms likely to be cultured in the near term. Of these, *Coccidioides immitis*, the causative agent of Valley Fever, and *Brucella spp.*, the causative agent of brucellosis, are regarded as incapacitating, rather than lethal, biological weapons and are unusual choices for defensive biological weapons work, particularly at a DOE facility. Both pathogens are readily treatable and rarely fatal. *Brucella spp.* is only known to have been weaponized by the U.S. and the former Soviet Union. It is thought that *Brucella spp.* was the first agent weaponized by the U.S., which has a long history and extensive knowledge of the agent and the disease that it causes.

16. Incapacitating agents, particularly those with long incubation periods like *Brucella spp.*, are extremely unlikely to be used against the U.S. A terrorist posing a biological threat will choose lethal agents over incapacitating ones. Militarily, incapacitating biological agents are far better suited for use to "soften" (weaken) a civilian population or an opponent's military prior to invasion with a large force. Using such a weapon against the United States simply is not practical, nor, since the disease produces only a low level of fatalities and is readily treatable, does it serve the purposes of terrorists.

17. Accidents and other safety and security problems have resulted from the expansion of research involving biological weapons agents. These include laboratory-acquired infections with biological weapons agents, unauthorized persons handling biological weapons agents, failure to account for stocks of biological weapons agents, and other problems. Due to a lack of transparency in this area, in general, it is only possible for the public to acquire information about laboratory mishaps in the limited number of cases where laboratories are (a) subject to open records rules sufficiently forceful to enable access to accident documentation and (b) have policies to record such incidents. There is mounting evidence that, at many facilities, there have been *de facto* policies not to record accidents, including accidents with biological weapons agents.

18. The following is a listing of accidents and other incidents involving select agents and/or BSL-3 labs prompted by the expansion of biological weapons agent research since 2002. Select agents are those biological agents and toxins designated by the Secretary of the Department of Health and Human Services ("HHS") as having "the potential to pose a severe threat to public health and safety." 42 C.F.R. § 73.3 (2005).

- In August-September 2005, Lawrence Livermore National Laboratory ("LLNL" or "Livermore Lab") was responsible for an anthrax release. On September 24, 2007, the Regents of the University of California, Lawrence Livermore National Laboratory agreed to resolve its liability for this alleged violation of the Select Agent Program. The HHS Office of Inspector General ("OIG") alleged that LLNL transferred vials of anthrax to two laboratories located in Florida and Virginia. During the transfers, anthrax was released from the approximately 4,000 shipped vials. Five workers were exposed to anthrax while unpacking the shipments and required treatment with the antibiotic Cipro for a week. As a result of this incident, CDC suspended all transfers of select agents, and Livermore Lab issued a full stand-down of all select agent work. CDC sent LLNL a report listing 29 points that needed to be addressed. It should be noted that this incident occurred while the prior lawsuit involving the proposed BSL-3 facility at Livermore Lab was pending, and LLNL failed to inform either the plaintiffs or the court of the anthrax release. The OIG specifically alleged that Livermore Lab violated the transfer requirements of the select agent regulations by failing to comply with the applicable shipping and packaging laws when transferring a select agent. In addition, the OIG also alleged that LLNL failed to comply with security and access requirements by allowing an individual not authorized to have access to select agents to package the shipments of anthrax, and that LLNL's Responsible Official—the individual designated by Livermore Lab with the authority and control to ensure compliance with the select agent regulations—failed to ensure compliance with the shipping and packaging requirements of the

select agent regulations. Under the terms of the settlement, LLNL agreed to pay the OIG $450,000 to resolve these allegations.

- Texas A&M University ("TAMU") is a Department of Homeland Security (DHS) National Center of Excellence in the study of biological weapons agents and is the lead institution in the DHS National Center for Foreign Animal and Zoonotic Disease Defense. Through the Texas Public Information Act, and significant pressure on TAMU officials, it was established that in 2006 and 2007 the University committed numerous violations of the Bioterrorism Act of 2002 (implemented by the select agent regulations). The most serious of these included an unreported lab-acquired infection with *Brucella sp.* and multiple unreported exposures to Q fever (*Coxiella burnetii*). CDC investigations prompted by Sunshine Project news releases documented additional serious violations that included more unreported lab exposures, irregularities in accounting for biological weapons agents, and, importantly, revelations that TAMU repeatedly permitted access to and handling of biological weapons agents by persons lacking federal permission to do so. In fact, the brucellosis victim was one such person.
- At the University of Wisconsin at Madison in 2005 and 2006, researchers handled genetic copies of the entire Ebola virus (called "full length cDNAs") at BSL-3, despite the fact that the NIH Guidelines require handling at BSL-4 because the genetic constructs had not been rendered irreversibly incapable of producing live virus. The University of Wisconsin at Madison Institutional Biosafety Committee reviewed and approved this research despite federal guidelines to the contrary. The problem was not detected by NIH. On the contrary, NIH funded the research.
- There is evidence that a situation similar to Wisconsin's exists or existed at Tulane University in New Orleans, Louisiana, which also does not have appropriate facilities for such research. Tulane officials refused a half dozen requests to clarify the research, again with Ebola cDNAs, as well as constructs for Lassa fever virus, another BSL-4 hemorrhagic fever agent.

- At the University of Texas at Austin in April 2006, human error and equipment (centrifuge) malfunction combined in an incident in a BSL-3 laboratory handling potentially very dangerous genetically-engineered crosses between H5N1 "bird flu" and typical (H3N2) human influenza. The researcher was placed on drugs, and the laboratory was shut down and decontaminated. The University did not report the incident to the federal government and has since produced conflicting accounts of exactly what happened.
- In mid-2003, a University of New Mexico (UNM) researcher was jabbed with an anthrax-laden needle. The following year, another UNM researcher experienced a needle stick with an unidentified (redacted) pathogenic agent that had been genetically engineered.
- At the Medical University of Ohio in late 2004, a researcher was infected with Valley Fever (*Coccidioides immitis*), a BSL-3 biological weapons agent. The following summer (2005), a serious laboratory accident occurred that resulted in exposure of one or more workers to an aerosol of the same agent.
- In mid-2005, a lab worker at the University of Chicago punctured his or her skin with an infected instrument bearing a BSL-3 biological weapons agent. It was likely a needle contaminated with either anthrax or plague bacteria.
- In October and November of 2005, the University of California at Berkeley received dozens of samples of what it thought was a relatively harmless organism. In fact, the samples contained Rocky Mountain Spotted Fever bacteria, classified as a BSL-3 bioweapons agent because of its potential for transmission by aerosol. As a result, the samples were handled without adequate safety precautions until the mistake was discovered. Unlike nearby Oakland Children's Hospital, which previously experienced a widely reported anthrax bacteria mixup, UC Berkeley never told the community.

19. In addition to laboratory-acquired infections and exposures, other types of dangerous problems have occurred at these facilities, such as unauthorized research, equipment malfunction, and disregard for safety protocols.

- In February 2005, researchers at the University of Iowa performed genetic engineering experiments with tularemia bacteria without permission. These experiments included mixing genes from tularemia species and introducing antibiotic resistance.
- At the University of Illinois at Chicago in September 2004, laboratory workers at a BSL-3 facility propped open doors of the laboratory and its anteroom, a major violation of safety procedures. An alarm that should have sounded did not.
- In March 2005, lab workers at the University of North Carolina at Chapel Hill were exposed to tuberculosis when the BSL-3 laboratory's exhaust fan failed. Due to deficiencies in the lab, a blower continued to operate, pushing disease-laden air out of a safety cabinet and into the room. An alarm, which would have warned of the problem, had been turned off. The lab had been inspected and approved by the U.S. Army one month earlier.
- In December 2005, three lab workers at the Albert Einstein College of Medicine at Yeshiva University in New York City were exposed (seroconverted) to the tuberculosis bacterium following experiments in a BSL-3 laboratory. The experiments involved a Madison Aerosol Chamber, the same device used in the February 2006 experiments that resulted in the Texas A&M brucella case, again underscoring the additional risks of research involving deliberate aerosolization of biological weapons agents.
- In mid-2004, a steam valve from the biological waste treatment tanks failed at Building 41A on the NIH Campus in Bethesda, Maryland. The building houses BSL-3 and BSL-4 laboratories. Major damage was caused, and the building was closed for repairs.

- In April 2007, a centrifuge problem exposed several laboratory workers at the University of Texas Health Science Center in Houston to anthrax.
- Also in April 2007, three laboratory workers entered a facility studying tularemia at the University of Texas at San Antonio to repair faulty air filters. The workers did not wear respiratory protection and handled the filter equipment without gloves.

20. It is very important to note that these and other examples of laboratory mishaps are drawn from biosafety committee meeting minutes of institutions that actually record such incidents in records that are—at least nominally—available to the public. Often, this is not the case, such as that of Texas A&M, which only released accident information under threat of indictment by the Brazos County, Texas District Attorney. Thus, the sample of institutions named above is (mostly) skewed toward those that have been more open about their mishaps than others.

21. There are major gaps in the oversight system for government and corporate laboratories. Lawrence Livermore National Laboratory recently delayed nearly 17 months before replying to a request for its Institutional Biosafety Committee ("IBC") minutes and then provided heavily and inconsistently redacted material that suggests significant problems handling biological weapons agents and with its laboratory equipment. The redactions are so heavy, however, that a more specific description of the problems cannot be discerned. IBCs are local committees operating under the NIH Guidelines for Research Involving Recombinant DNA Molecules. By grant contract, IBCs are mandatory for institutions receiving NIH funding involving recombinant DNA (genetic engineering) and for certain other laboratories by departmental rule or regulation. It is also federal policy that IBCs review not only genetic engineering projects but also those involving biological weapons agents.

22. Also, there are major gaps in the assumptions underlying the accident analysis in the final Revised EA for the proposed BSL-3 facility at Livermore Lab. For example, on page 51, the final Revised EA states that "[a]ccident scenarios usually envisioned for DOE facilities would normally be seen to exacerbate or enhance a release or spread of the hazardous materials, but for the BSL-3 facility would potentially render these materials innocuous (hear, fire, sunlight and

wind). These would be avoided when working with microorganisms and would usually result in microorganisms being killed. Consequently, catastrophic events such as earthquake, fire, explosions and airplane crashes, normally considered as initiating events in DOE radiological or chemical accident analyses, were viewed as having the potential to actually reduce the consequences of microbial material releases. An earthquake, explosion, or similar event that would result in a breech [sic] or rupture of the facility's walls would be bounded by the hypothetical centrifuge-accident analysis of a *Coxiella burnetii* release for the proposed BLS-3 facility structure . . . ."

I declare under penalty of perjury that the foregoing is true and correct, and if called as a witness I could competently testify hereto.

Executed on (date) 3/10/08, (city) Livermore, (state) California

EDWARD HAMMOND
(approved telephonically)

EXHIBIT 2

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

TRI-VALLEY CARES, MARYLIA KELLEY, JANIS KATE TURNER, and JEDIDJAH DE VRIES, Plaintiffs, vs. UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION, and LAWRENCE LIVERMORE NATIONAL LABORATORY, Defendants	Case No.: DECLARATION OF MARYLIA KELLEY IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, Marylia Kelley, declare as follows:

1. I am a named plaintiff in this action, and I have personal knowledge of the following and could and would competently testify thereto if called upon to do so.

2. I am Executive Director of Tri-Valley CAREs (Communities Against a Radioactive Environment), a California non-profit corporation based in Livermore, California and founded in 1983, that is a plaintiff in this action. I am a co-founder of Tri-Valley CAREs and have served as its Executive Director for most of the group's 25 years.

3. The Department of Energy's (DOE) Lawrence Livermore National Laboratory (LLNL or Livermore Lab) was founded in 1952 and is one of the country's two principal nuclear weapons design labs.

4. As Tri-Valley CAREs' Executive Director, I serve on the LLNL-sponsored Community Work Group (CWG) to advise state and federal regulatory agencies, DOE and Livermore Lab on the "Superfund" cleanup of toxic and radioactively contaminated soil and groundwater at the site, some of which is emanating into the Livermore community. LLNL was named to the federal Environmental Protection Agency's National Priorities List (also called the "Superfund") in 1987. I have held a seat on the CWG since its inception in 1989. I was invited by state and county health officials to sit on the Alameda County plutonium sludge task force to address the public's questions and potential hazards posed by the distribution of sewage sludge contaminated with plutonium from LLNL. I was appointed by Congressman Ron Dellums to serve on the East Bay Conversion and Reinvestment Commission to advise it on LLNL programs. I have served in similar capacities on other advisory boards and commissions.

5. In my role as Tri-Valley CAREs' Executive Director, I have also testified on the environmental and health impacts of LLNL programs to committees of the California legislature, the National Academies of Science and other administrative, law-making, technical and scientific bodies.

6. I and other Tri-Valley CAREs staff, board and members reviewed the draft Revised Environmental Assessment for the DOE's proposed Biosafety Level 3 (BSL-3) facility at LLNL

and offered public comments on it. This process was made difficult because DOE did not publish in the draft Revised Environmental Assessment a postal address, email address or fax number to which members of the public could send comments. Nor was the due date for public comment published in that document. These crucial pieces of information were limited to the DOE press release. Tri-Valley CAREs requested that DOE remedy the situation and extend the public comment period, but the agency refused to do so. Nor did DOE take the modest step of informing those members of the public who had submitted comments on the original Environmental Assessment that a draft revised version was available for comment.

7. Tri-Valley CAREs took numerous steps to inform the public of the comment process and of where to send comments, although the 30-day period meant that the deadline had passed by the time our monthly newsletter, sent bulk mail, reached many of our members. Further, the DOE facsimile number listed in their press release did not operate on May 11, 2007, the final day of the comment period (and perhaps did not operate earlier). I have personal knowledge that the DOE facsimile number was out of commission on May 11 because approximately 13 people called or came to the Tri-Valley CAREs office that day to alert us to the problem they were encountering. I repeatedly called the DOE document manager in charge of the process and also emailed him, but received no response that day. I later learned that he was not in the office at all on May 11. I know of at least one member of the public who gave up and at least one other who had assumed her fax to DOE went through when it could not have. I believe that this series of obstacles to public comment may have prevented other members of the public from participating.

8. I and other Tri-Valley CAREs staff, board and members have reviewed the subsequent final Revised Environmental Assessment (EA) and Revised Finding of No Significant Impact (FONSI) for the proposed LLNL BSL-3 facility. I and other Tri-Valley CAREs staff, board and members have participated in all administrative proceedings related to the BSL-3 facility at LLNL.

9. I and other Tri-Valley CAREs staff, board and members have been denied any public hearing(s) on the LLNL BSL-3 facility and the more thorough, high-level environmental review we believe is necessary to protect our health and the environment from the scores of potentially

deadly bio-warfare agents that, according to the EA, may be transported, stored, used, replicated, genetically modified, and aerosolized (sprayed) in the LLNL BSL-3 facility and that may become available to or a target of terrorists.

10. Most staff, board and members of Tri-Valley CAREs, including named plaintiffs Janis Kate Turner and Jedidjah de Vries, live or work in the vicinity of Livermore Lab. We are harmed by the increased risks to public health, safety and security posed by the start-up and operation of the LLNL BSL-3 facility in the absence of an adequate environmental review. We are harmed by the heightened threat that housing up to 50 liters of dangerous pathogens—including anthrax strains famous for their special virulence (like the Vollum strain), plague, Q Fever, and other agents and toxins historically used in biological warfare—will make LLNL a more likely target of terrorism.

11. I reside on East Avenue in the City of Livermore, approximately one-quarter mile from LLNL. I have lived at my current address since 1978. There are approximately 100 family units with 2 to 4 bedrooms each in my complex. Going east from my home to Livermore Lab, you will see a large, low-income apartment complex and then closely packed single-family homes built right up to the southwest boundary of LLNL. Other densely packed neighborhoods, along with a City park and little league fields, are also adjacent to Livermore Lab. I live in a heavily populated area—there are more than 81,000 people residing in Livermore, California, and the population is growing. There are more than 7 million people living within a 50-mile radius of LLNL.

12. Over the 30 years I have lived at my current address, the population has swelled toward and around LLNL. There are multiple new housing developments that have been built directly across the street from the LLNL fence line, and new homes are still under construction in the immediate vicinity.

13. Traffic on Vasco Road, my access route to Interstate 580 (I-580) and LLNL's western boundary, is routinely extremely busy due to the many vehicles associated with residents from the new housing, LLNL's approximately 8,000 workers, and other traffic from the new office buildings and other new construction around LLNL. During commute hours in particular, I-580

is now routinely at or near a standstill due to these and other traffic increases that have occurred during the time that I have lived at my current address. In the event of a release of deadly biological agents from the LLNL BSL-3 facility, any attempted evacuation would be chaotic if not impossible to accomplish in a timely manner, and the disruption (e.g., potential closure of I-580 and offices and businesses in the area) would be extreme.

14. I and Tri-Valley CAREs staff, board and members, along with Livermore Lab workers and the community at large, have been directly and adversely affected by past and current LLNL operations and fear additional harm from operation of the proposed BSL-3 facility.

15. Nuclear weapons work at LLNL has led to pollution released to the air, land, surface waters and groundwater, including plutonium (the radioactive core element of nuclear weapons), tritium (radioactive hydrogen), hexavalent chromium, Freon, volatile organic compounds like TCE, and numerous others. There is an off-site contaminated groundwater plume emanating from LLNL. Part of that off-site contaminant plume includes the groundwater beneath my home, which is being cleaned up under the aforementioned Superfund program that will need to continue for decades to come. For years, the creek behind my home where my son and his friends played received contaminated run-off from LLNL. Documented airborne releases of radioactivity from Livermore Lab total about 1 million curies. One curie is a large amount of radiation, equaling 37 billion radioactive disintegrations per second. The rainwater on-site at Livermore Lab and off-site in neighborhoods, including mine, has been found to contain elevated levels of tritium, with spikes as high as 7 times the state and federal maximum contaminant level for drinking water. Elevated levels of plutonium from LLNL were found in the top two inches of soil at a City park west of LLNL and in an off-site air monitor east of LLNL. For twenty years, sludge from the City sewage treatment plant, contaminated by plutonium that was dumped down LLNL drains, was given away to unsuspecting residents for use in their gardens and lawns.

16. There have been hundreds of documented violations of environmental, health and safety rules, regulations and laws at LLNL. The documentation is in state and federal notices of violation, regulatory agency inspection and enforcement reports, compliance orders, legal proceedings, DOE notices and LLNL reports, among other sources. These violations include

criticality safety violations. A criticality accident is an unplanned, runaway nuclear chain reaction. In one documented event, LLNL suffered a criticality accident involving nuclear weapons grade uranium. One of the workers said, "We heard an explosion and evacuated the building." An uncontrolled fire raged in the mass of molten uranium and scientists feared a second, larger blast. The community, it was said, was "lucky" that day.

17. HEPA filters have been breached at Livermore Lab, leading to radioactive releases. Equipment has malfunctioned in ways that LLNL could have but did not anticipate and this has led to releases from the tritium facility and other operations. Equipment known to be faulty has been used nonetheless and has led to contamination. In one case, a plutonium glove box with a missing seal was left in operation, and when plutonium was released the room's air alarm failed. Days later, elevated levels of plutonium were recorded in a hallway monitor outside the room. Fires with uranium, curium and other materials have erupted. Chemical products that were not supposed to be in wastes according to LLNL procedures were present in wastes, and this has led to incompatible wastes mixing with explosive results. Some wastes were never recorded but were buried in the ground at LLNL. Later construction projects accidentally unearthed unlisted dump sites full of hazardous debris.

18. These toxic and radioactive incidents are not vestiges of past practices, but continue to the present. On February 20, 2008, Livermore Lab held a meeting with construction workers because LLNL had exposed at least 178 of them to the toxic metal Beryllium without their knowledge. The workers had been doing a multi-year seismic retrofit and renovation in one of the machine shops at LLNL. In February 2007, tests done by Livermore Lab showed Beryllium contamination in the machine shop. Officials at LLNL kept the results secret and allowed work to continue. A second round of tests was conducted in July 2007. It too showed Beryllium contamination present in the building. Unsuspecting employees were allowed to work in at least one of the Beryllium-contaminated buildings until September 2007, months after LLNL management knew of the risks being incurred. In all, LLNL admits that three buildings showed Beryllium contamination (the aforementioned machine shop plus two others), so the number of workers potentially exposed exceeds the 178 construction workers. There are still many

unanswered questions about the number of workers exposed, procedural violations, the role of secrecy, and how and why avoidable exposures were allowed to continue.

19. I and the staff, board and members of Tri-Valley CAREs fear, and suffer harm from, the LLNL culture in which violations of procedures and regulation—and lax attitudes about safety and security—are tolerated in practice and the results are kept under wraps. This harm underscores the importance that I and others in Tri-Valley CAREs and the community place on obtaining public hearings and a thorough, comprehensive and objective analysis of potential terrorism and other risks associated with the LLNL BSL-3 facility, which the agency must consider alongside mitigation measures to address those risks. We believe that absent this higher level of review and opportunities for public participation, the root conditions that facilitate the accidents, spills, breaches and leaks with toxic and radioactive materials at other LLNL buildings and programs may lead to similar outcomes in the proposed BSL-3 facility at Livermore Lab.

20. This harm is exacerbated by the fact that the existing LLNL biological buildings and programs have themselves been the scenes of bio-accidents, spills, leaks, breaches, procedural deficiencies, security violations and a lack of openness or disclosure.

21. On October 4, 2007, while the House Energy and Commerce Committee held a hearing on the safety and security of the nation's biodefense research laboratories, it came to light that researchers at Livermore Lab mishandled anthrax, breached security and access requirements, and violated shipping laws leading to a release of anthrax. The incidents resulted in a $450,000 fine, which was levied by the Department of Health and Human Services (DHHS). According to the DHHS and its website, this was the largest fine levied up to that date for an accident involving a pathogen historically associated with bio-weapons. The incidents and release occurred in August-September 2005.

22. The violations and fine were related to 2 different shipments of anthrax from LLNL, according to the DHHS Office of the Inspector General. In one case, 1,025 vials of anthrax were shipped from LLNL to Palm Beach, Florida. Two of the anthrax vials did not have any caps (i.e., they were opened and spilled) and a third had a loose twist cap. Workers in Florida who unknowingly opened the package which contained the anthrax vials were potentially exposed

and had to be placed on the antibiotic Cipro for a week before they could return to work. A second anthrax package, sent from LLNL on the following day, contained 3,000 vials of anthrax, too much pathogen for the package and a violation of regulations.

23. A LLNL researcher, who was not authorized to handle potentially lethal bio-agents like anthrax, packed both shipments. Further, the biosafety officer whose responsibility it was to supervise the packaging operation failed to do so. These are both security breaches. This disregard for security could have led to a diversion or deliberate release of the pathogen. It not only violated government regulations but raised the risk that Livermore Lab's handling of biological agents at its Biosafety Level-2 facility may increase the threat that a terrorist could access anthrax at Livermore Lab. The operation of the LLNL BSL-3 facility greatly exacerbates and elevates this risk. A BSL-3 facility allows LLNL researchers access to and use of aerosolizable (sprayable and easily made airborne) forms of anthrax and numerous other deadly bio-warfare agents that require management at BSL-3, as well as genetically modified pathogens that may have novel features of special interest to a terrorist.

24. At the time of the 2005 LLNL anthrax incident, Tri-Valley CAREs and co-plaintiffs were pursuing NEPA litigation challenging the adequacy of the DOE's December 2002 final EA and FONSI for the LLNL BSL-3 facility. The final EA in essence concluded that no harm to human health or the environment would occur at the LLNL BSL-3 because of the numerous safety and security procedures in place. That final EA is the foundation for and contains the vast majority of the text and analysis found in the present final Revised EA for the LLNL BSL-3 facility. The DOE did not inform Plaintiffs, the United States District Court for the Northern District of California or the Ninth Circuit Court of Appeals about the 2005 anthrax incident at any time during that NEPA suit, which was terminated on June 1, 2007.

25. The DOE continued to keep the not-yet-public anthrax mishap under wraps. In the draft Revised EA for the LLNL BSL-3 facility, released April 11, 2007, the agency chose to characterize it as merely a minor violation of shipping and packaging requirements. The draft Revised EA did not mention anthrax at all. Nor did it mention that a pathogen was released. Nor did it disclose that workers had to be placed on protective drugs due to potential exposures.

26. Further, the draft Revised EA did not reveal that security violations were incurred or that an unauthorized person was given access to thousands of vials of a bio-weapon agent, even though the Ninth Circuit Court of Appeals had remanded the matter for DOE to conduct a NEPA-compliant terrorism analysis and determine if an Environmental Impact Statement was the appropriate level of review. Nor did the draft Revised EA mention that the LLNL Responsible Official, who is supposed to ensure compliance with the select agent regulations, failed to do so.

27. On October 9, 2007, less than a week after the LLNL anthrax incident became public, Tri-Valley CAREs submitted a Freedom of Information Act request to the DOE, requesting records regarding the anthrax release and violations by LLNL. As of March 6, 2008, I have yet to receive any documents or substantive response from the agency.

28. On October 29, 2007, soon after the violations became public but more than five months after the May 11, 2007, comment deadline for the draft Revised EA, the Tri-Valley CAREs Staff Attorney and I sent a letter to DOE outlining the way the anthrax incident had been mischaracterized in the draft Revised EA. We pointed out that our members and others in the community are harmed by this omission and would have considered information about the anthrax release and the security violations significant when commenting on the proposed BSL-3 facility, which DOE acknowledges will handle even deadlier select agents and require increased shipments into and out of Livermore Lab. Our members and others in the community would also have commented on the recent proliferation of BSL-3 facilities and the safety and security concerns regarding these facilities, as well as a report on biological weapons and the bioterrorism threat authored by Milton Leitenberg and the aforementioned Beryllium exposure, depending on the timing. We asked DOE to re-draft the EA and re-circulate it for public comment. We also asked the agency to hold a public hearing and we renewed our call for the DOE to prepare an Environmental Impact Statement. The DOE chose "none of the above" and did not respond directly to our letter.

29. The 2005 anthrax incident is not the only biological accident or release at LLNL. On February 23, 2006, the DOE issued LLNL a "Preliminary Notice of Violation and Proposed Civil

Penalty of $588,500 (Waived by Statute)." Part 2 of the February 2006 Notice of Violation describes an accident that occurred in the main LLNL biological programs building. The violation is titled, "Phosphorus-32 Spread of Contamination Event." It describes an accident in Building 361, which is directly adjacent to the proposed LLNL BSL-3 facility, which can be seen on the map on page 10 of the EA.

30. The February 2006 notice cites biological personnel violations of law and procedure. Under "Control of Material and Equipment Violation," it cites violations of 10 C.F.R. § 835 (multiple sections) and LLNL's Environmental Safety and Health (ES&H) Manual 20.2 (multiple sections).

31. The document describes a radiological spill involving 10-15 milliliters of solution from a glass container holding radioactive phosphorus labeled DNA probes. According to the Notice of Violation: "The event occurred during a routine laboratory procedure in Building 361. The appropriate qualified LLNL personnel failed to respond to the spill after being notified on April 22 to ensure that the source of the spill was adequately controlled. Both the worker and laboratory contaminated area were not surveyed in a timely manner by qualified individuals to adequately determine the extent of the contamination and to develop appropriate response and controls. The inadequate response resulted in inappropriate removal of radioactive material from the site and radiological conditions that were in an unknown status for several days (from Friday, April 22 until the following Monday, April 25)."

32. The 2006 Notice of Violation specifies that the "inappropriate removal of radioactive material from the site" refers to the worker tracking contamination as he left work. The report states, "a researcher, with his supervisor's authorization, took a known contaminated item (shoe) from the LLNL site in violation of these release criteria and other applicable controls. The shoe was subsequently determined to exceed 10 C.F.R. § 835 appendix D criteria with a contamination level of 148,000 dpm/100 cm(2)." It is not known whether security personnel or other workers present over the weekend were exposed to the unexamined radioactive spill. The DOE notice calls that question an "unknown status."

33. In 2003, I filed a Freedom of Information Act Request for responsive documents involving accidents in LLNL biological programs and facilities. Among the documents received is an incident report detailing a series of mishaps in March 1999 with airborne *Bacillus anthracis*, the causative agent for anthrax. On March 1, 1999, experiments indicated that LLNL was mistakenly conducting experiments with a virulent strain of *Bacillus anthracis* obtained from a "colleague." LLNL did not terminate operations with the organism until March 5, 1999. The Institutional Biosafety Officer was not notified until March 17. The report's 13 findings include that "[t]he Biomedical Technician did not use engineering controls and mistakenly disposed of contaminated equipment and utensils in the trash." The findings also specify that "Access Control" was not maintained and "cross contamination" with nearby food was possible.

34. Also in response to the FOIA request was an occurrence report detailing an accident in which a LLNL bio-lab employee sent improperly labeled waste to the LLNL hazardous waste facility.v The waste was listed as "99% laboratory trash (with 2-mercaptoethanol, phenol and chloroform)." However, the bag improperly contained "at least two hypodermic needles that were not listed on the label." As a result: "One of the needles penetrated the bag and stuck the technician in his arm."

35. The harms from Livermore Lab nuclear, chemical and biological activities that may be replicated in type if not in precise detail in the proposed LLNL BSL-3 facility in the absence of openness, further NEPA review and mitigation measures, include health impacts suffered by workers as well as community members. Tri-Valley CAREs facilitates regular support group meetings for LLNL workers who have been made ill by on-the-job exposures to toxic and radioactive materials. The federal government admitted in 2000 that it had routinely lied to atomic workers about the risks posed by the materials they were required to handle. The Energy Employees Occupational Illness Compensation Program Act then became law. Since 2000, more than 2,312 claims have been filed by ill LLNL workers or their survivors. There is no claims program for community members who may have become ill due to LLNL accidents, spills, breaches and releases. But independent studies that have been conducted in Livermore demonstrate a measurable health problem in the community. In 1995, the California Department

of Health Services – Environmental Health Investigations Branch (CDHS-EHIB) released a 30-year study of Livermore children that focused on five cancers. It found that children born in Livermore had 6 times the expected incidence of malignant melanoma. Children who were not born in Livermore but moved there experienced a malignant melanoma incidence rate that was more than double the expected rate. The 1995 study also found an elevation in childhood brain cancers for one ten-year period. An earlier CDHS-EHIB study found a 5-fold increase in malignant melanoma among LLNL employees, which it correlated with workplace factors.

36. The proposed LLNL BSL-3 facility is controversial in the community. LLNL workers and community members have expressed health worries about the BSL-3 facility. The DOE decision to locate the proposed facility at the Main Site where the nearest active earthquake fault zone crosses less than 200 feet from the site boundary is controversial, as is the decision to house it in a portable building. Community members, LLNL workers and retirees have, along with non-DOE scientists, debated the outcomes of accidents in the proposed LLNL BSL-3 facility. Moreover, the quantities of deadly pathogens that will be housed and used in the BSL-3 facility are controversial in the community and with numerous LLNL employees, as are plans to genetically modify bio-warfare agents and conduct aerosol "challenges" on up to 100 small animals at a time. The novel nature of the experiments in contrast to a typical medical BSL-3 facility generates controversy.

37. The proposed LLNL BSL-3 facility is controversial within the scientific community. Scientific controversy exists regarding the health impacts of the proposed facility, the problems associated with its HEPA air filters and the pathogens that will escape into the outside environment through them, the large inventory of biological agents that will be housed in the facility, the genetic modification of agents that will take place in the BSL-3 facility and the likelihood that a novel pathogen will result (which could need BSL-4 containment as well as elevate the security risks and threat of terrorism), the hazards posed by the aerosol experiments in the facility and the elevated risks to security and terrorism they represent, the ground motion associated with earthquakes that will impact the LLNL BSL-3 facility, and the impact of the proposed facility on international perception, the Biological Weapons Convention and the global

proliferation of bio-weapon programs and bio-weapons. Despite the DOE-generated impediments to public comment and the agency's refusal to extend the public comment period, I encouraged scientists and other experts who discussed these controversies with me to submit their comments in writing on the draft Revised EA. In at least one case, a scientist was deterred from commenting by the aforementioned unworkable DOE facsimile machine. In other cases, written comments were submitted, but were swept aside by DOE and not adequately or objectively considered in the EA.

38. The collocation of "bugs and bombs" in a highly classified facility devoted to the development of nuclear weapons of mass destruction is controversial within the community and among U.S. scientists—and also around the globe. Over the past 3 years, Tri-Valley CAREs has sent a representative to some of the Meetings of the States Parties to the Biological Weapons Convention, held at the United Nations in Geneva, Switzerland, where diplomats have expressed serious concern about the LLNL BSL-3 facility, as have scientific experts attending the meetings and non-governmental organizations. There is agreement the experiments in the LLNL BSL-3 facility will complicate the negotiations toward strict verification and enforcement protocols for the Biological Weapons Convention, and thus weaken it. There is also considerable debate about whether certain experiments will also violate the treaty's provisions—and how the public or other nations will know of such violations should they occur.

39. The risks of terrorism are likewise much more controversial and complex than DOE considered in the EA. There is debate in the community and among scientists and other experts about whether this BSL-3 facility puts LLNL on the terrorist map in new ways. LLNL employees, including LLNL security personnel, have expressed this concern to me. While the EA concludes in essence that an explosion caused by terrorism will kill off the dangerous biological agents before they can infect anyone, independent and LLNL scientists alike have pointed out to me that bio-weapons, including some of our nation's former bio-weapons, contain an explosive mechanism to spread the pathogens. Some biological agents may die in an explosion, but some may be spread by it. Moreover, there is controversy and discussion in the community and among scientists and others, including LLNL security personnel, about whether

LLNL is adequately prepared for a terrorist attack on the bio-facility and which scenarios people believe may have the best chance of succeeding.

40. The ramifications of an airplane crashing into the proposed LLNL BSL-3 facility are brought up often and debated by community members, scientists and others. According to the City's web site, the Livermore municipal airport boasts 240,000 aircraft operations each year—and LLNL is in one of its main flight paths. Additionally, LLNL is in the flight path for some "jumbo" jets on their way to the Oakland airport. I have been on flights passing over LLNL on the way to Oakland's airport.

41. The risk of terrorism, the costs of trying to defend against it and the extremely close proximity of large, densely-populated neighborhoods to the LLNL fence line have prompted DOE to announce that it will remove all weapons-usable quantities of plutonium and highly enriched uranium from LLNL.

42. The DOE announced its decision to remove all Category I and Category II special nuclear materials out of Livermore Lab by the end of 2014 at a House Armed Services Strategic Forces Subcommittee hearing in April 2006. Just prior to that decision, the agency released a plan to install high tech military Gatling guns at LLNL that could fire at a rate of up to 4,000 rounds per minute with a kill zone of a mile or more, which may put them in neighborhoods, parks and schools.

43. In November 2007, the U.S. Government Accountability Office (GAO) released a report titled, "The DOE has made little progress consolidating and disposing of special nuclear material." In the report, the GAO estimated that DOE would need to spend nearly half a billion dollars attempting to secure LLNL's plutonium until 2014 from a terrorist attack. In December 2007, the head of the DOE National Nuclear Security Administration announced during a press conference at which I was present that LLNL was not an appropriate site for plutonium to be located. The DOE, he said, would accelerate its schedule and remove all weapons-usable quantities of the deadly material out of LLNL by 2012, two years earlier than previously planned.

44. The plutonium at LLNL is housed in a specially reinforced plutonium facility inside an area known as the "Superblock." The "Superblock" has double fences around its perimeter, guard towers and extra security measures, none of which are present at the LLNL BSL-3 facility, which is housed in a portable building in an area with other LLNL employees, contractors, visitors and more going in and out of multiple buildings that are all around the BSL-3 facility and use the same parking lot, road and walkways.

45. If LLNL is not considered by DOE any longer to be a safe and secure location to house plutonium and enriched uranium and may be vulnerable to a terrorist bent on accessing weapons usable quantities of nuclear materials, that same level of careful analysis should have been brought to bear on the LLNL BSL-3 facility in the final Revised EA—but was not.

46. *Coxiella burnetii*, the agent that causes Q Fever, is listed in the EA and is one of many potentially deadly biological agents that will be handled in the proposed BSL-3 facility. The microorganism measures about 0.2 micrometers. According to the Centers for Disease Control and Prevention, and cited in the EA, 10 microorganisms are sufficient to cause illness. The EA for the LLNL BSL-3 discusses *Coxiella burnetii* and other microorganisms in culture of one-liter quantities in each of the three BSL-3 labs within the BSL-3 facility. At the concentrations specified in the EA, a single liter of *Coxiella burnetii* would contain enough microorganisms to cause illness in 10 billion people. If a person is made ill due to plutonium exposure, he or she will suffer the outcome, but cannot spread it to others. Plutonium is radioactive, not contagious. We in the community face the harms imposed by the multiplier effect if the pathogen released from the proposed LLNL BSL-3 facility causes a contagious illness. In addition to other grave shortcomings, the EA offers blithe assurance in place of careful analysis of disease transmission once it is out in the community.

47. The DOE is also analyzing terrorism risks and other hazards at the LLNL BSL-3 facility to a lower standard of review than it is undertaking for a similar proposal to construct and operate a BSL-3 facility in the future at the Los Alamos National Laboratory in New Mexico, a more remote, inaccessible, terrorism-resistant and less seismically active location than LLNL. Before moving forward with a proposed BSL-3 facility at the Los Alamos National Laboratory,

the DOE is undertaking a full Environmental Impact Statement and public hearings, which is the level of NEPA review and public participation that Tri-Valley CAREs believes is needed for the proposed LLNL BSL-3 facility.

48. On September 19, 2007, Tri-Valley CAREs' Staff Attorney and I sent a letter to DOE reiterating our organization's position that NEPA requires the DOE to prepare an EIS for the proposed LLNL BSL-3 facility, and that should the DOE choose, albeit improperly, to issue a FONSI for the proposed facility, DOE's own regulations require that a draft FONSI be circulated for public review and comment before a final determination is made whether to prepare an EIS and before the action may begin. In the same letter, we pointed out that the U.S. Nuclear Regulatory Commission had recently published a supplemental Environmental Assessment and draft FONSI for a spent fuel storage facility under construction at the Diablo Canyon nuclear power plant in San Luis Obispo County, California, which included a 30-day public comment period. The Nuclear Regulatory Commission had been forced to conduct the supplemental assessment after the Court of Appeals for the Ninth Circuit held that an Environmental Assessment that does not consider the environmental effects of a terrorist attack is inadequate. Likewise, the Ninth Circuit held that the DOE's 2002 Environmental Assessment for the proposed LLNL BSL-3 facility was inadequate because it contained no consideration of the effects of a terrorist attack. Once again, the DOE not only violated its regulation, but also chose a lower standard of review for a similar issue than its "sister" agency, the Nuclear Regulatory Commission.

49. In calendar and fiscal year 2006, the most recent full year for which financial records such as Form 990 are available, Tri-Valley CAREs' income from all sources totaled $291,637.

50. In the same year, 2006, Tri-Valley CAREs' expenses totaled $298,618.

51. Tri-Valley CAREs' net worth, as of March 3, 2008, is $135,957.

52. In light of the above, it would not be possible for Tri-Valley CAREs to post a substantial bond.

I declare under penalty of perjury that the foregoing is true and correct, and if called as a witness I could competently testify hereto.

Executed on (date) March 10, 2008, (city) Livermore, (state) CA.

Marylia Kelley

MARYLIA KELLEY

EXHIBIT 3

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

TRI-VALLEY CARES, MARYLIA KELLEY, JANIS KATE TURNER, and JEDIDJAH DE VRIES, Plaintiffs, vs. UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION, and LAWRENCE LIVERMORE NATIONAL LABORATORY, Defendants	Case No.: DECLARATION OF MARK WHEELIS, PH.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, Mark Wheelis, declare as follows:

1. I am a Senior Lecturer Emeritus in the Department of Microbiology at the University of California, Davis (UCD). I received my Ph.D. in Bacteriology from the University of California at Berkeley in 1969. After a year of postdoctoral work in Biochemistry at the University of Illinois, I took my current faculty position at UCD, retiring March 1, 2008. I am trained as a microbial biochemist and geneticist. For the last 20 years my research has focused on the history of biological and chemical warfare, and on biological and chemical weapons control. My resume (attached hereto) summarizes my publications, educational background, and recent professional activity.

2. I have been a member of the Scientists Working Group on Biological and Chemical Weapons ("the Working Group"), of the Center for Arms Control and Nonproliferation (CACNP), for over 15 years, and have been its Chair since January 2008. The CACNP formed in 1980, and has been a leader in all the key chemical and biological arms control debates of the late 20th and early 21st centuries. Based in Washington D.C., the CACNP provides technical advice to policy makers (both U.S. and international) on chemical and biological arms control issues. Previously, the Working Group was affiliated with The Federation of American Scientists, a nonprofit organization founded in 1945 by members of the Manhattan Project.

3. The Working Group consists of experts in a variety of fields who volunteer their services. It develops papers and reports on technical and policy issues and holds seminars and briefings for U.S. and international officials. The Working Group program covers all aspects of chemical and biological weapons and their control, including efforts to prevent the development and use of biological weapons (BW) and the further proliferation of BW programs. Major interests of the Working Group include strengthening the Biological Weapons Convention (BWC), cooperative measures for the global prevention of infectious disease, ethical education of biologists, and transparency in the U.S. biodefense program and anti-bioterrorism policies.

4. I am familiar with the Department of Energy's (DOE) Chemical and Biological National Security Program (CBNP) and with DOE's final Environmental Assessment (EA) to construct

and operate a BSL-3 facility at the Lawrence Livermore National Laboratory (LLNL). Based on my expertise in the area of microbiology and biological weapons control, it is my opinion that the work proposed to be conducted at the BSL-3 facility at LLNL—one of the two primary U.S. nuclear weapons design and development laboratories—creates a significant risk of proliferation of biological weapons. This proliferation risk constitutes a security risk to the U.S. and increases the potential harm to the environment and the public. The proposed facility may also constitute a hazard to the surrounding community. The EA does not adequately address the significant proliferation and biosafety risks posed by operation of this facility.

The DOE BSL-3 at LLNL is Different From Typical Medical BSL-3 Facilities

5. At the proposed LLNL BSL-3 facility, the quantities, concentrations, the genetic modification of and the aerosolization of biological select agents are distinctly different than at most BSL-3 facilities in hospitals, universities, and other civilian research organizations in California and the country. LLNL is a military laboratory with a major portion of its budget devoted to the design and development of nuclear weapons. According to the DOE budget request for fiscal year 2009, transmitted to Congress on February 4, 2008, the percentage of the LLNL budget that will be dedicated to weapons activities in the coming year exceeds 85% of the total (i.e., $950 million of $1.1 billion).[1]

6. Civilian and medical biosafety facilities typically do not store, work with or aerosolize the same quantities and concentrations of bioagents as are proposed for the LLNL BSL-3 facility. Aerosolization of select agents is a form of weaponizing these bioagents, and it makes these agents far more dangerous due to accidental occupational exposure and, in the case of a failure of containment, exposure of civilians outside the facility.

Consideration of Potential Releases from the LLNL BSL-3 is Incomplete

[1] Department of Energy FY2009 Congressional Budget, Laboratory Table, LLNL, pp. 45-47.

7. In April and May 1979, an unusual anthrax epidemic occurred in Sverdlovsk, a city of 1.2 million people located 1400 kilometers east of Moscow in the former Soviet Union. The epidemic occasioned an intense international inquiry into its origins, including by the U.S.

8. Following research, interviews and reconstruction of events, wind patterns, etc., it has been determined that an accidental release of anthrax had occurred on April 2, 1979. The outbreak resulted from the windborne spread of an aerosol of anthrax spores, and the source was the military microbiology facility at Sverdlovsk. This incident appears to have been caused by operator error in removing a HEPA filter and not replacing it. It is estimated that between 2 and 600 milligrams of dried anthrax spores were released. The human fatalities extended for approximately 4 kilometers downwind of the Sverdlovsk facility, and over 100 people died as a result of the accident. Veterinary cases occurred as far as 50 km downwind of the source.[2]

9. The Sverdlovsk experience provides instruction as to the amount of attention to and scope of the accident analysis that should be undertaken for the LLNL BSL-3 in its National Environmental Policy Act (NEPA) review, although the EA does not include it. Some of the critical factors that made the 1979 Sverdlovsk release so severe, such as the potential for aerosolization, worker error and HEPA filter issues, a nearby population center, and a relatively large quantity of inventory are, in general terms, also present at the LLNL BSL-3 facility.

10. The EA states that aerosolized pathogens will be used to conduct animal challenges on up to 100 small animals at a time, specifically on mice, rats and guinea pigs. However, it does not provide sufficient detail to determine how large an aerosol will be produced, what the concentration of pathogens in the aerosol will be, or how long aerosols will be kept or how they will be destroyed. There is no analysis of the possible consequences of natural disaster (e.g., earthquake) or terrorist attack during the conduct of aerosol experiments, despite the lesson of Sverdlovsk that milligram quantities of aerosolized anthrax spores can cause significant

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[2] Matthew Meselson, Jeanne Guillemin, Martin Hugh-Jones, Alexander Langmuir, Ilona Popova, Alexis Shelokov and Olga Yampoloskaya, "The Sverdlovsk Anthrax Outbreak of 1979," Science, Vol. 266, published by the American Association for the Advancement of Science, Nov. 18, 1994, pp. 1202-1208; Matthew Meselson, "Note Regarding Source Strength," The Applied Science and Analysis Newsletter, June 8, 1995, pp. 1, 20-21.

mortality in surrounding communities. There is also no consideration of the possibility that such natural disaster or terrorist attack could lead to the release of material trapped in HEPA filters.

11. Furthermore, the EA gives only cursory mention of the possibility of agent escape from the facility via arthropod vectors. Some of the diseases (e.g. plague) to be studied at the facility are, or can be, vector-borne. The potential for disease transmission to the surrounding community by vectors should be considered. No detail is given of the proposed pest control program, so it is not possible to evaluate whether it is adequate. Rat fleas, for instance, could be inadvertently carried out of the facility by workers, and workers could import fleas from their own pets.

12. LLNL has already demonstrated that it has inadequate oversight over its mailings of pathogens. In 2007, the Inspector General of the U.S. Department of Health and Human Services cited LLNL's biological program for violating transfer requirements of the select agent regulations by failing to comply with the applicable shipping and packaging laws when transferring a select agent. The Office of the Inspector General states that "LLNL transferred vials of anthrax to two laboratories located in Florida and Virginia. During the transfers, anthrax was released from the shipped vials." LLNL paid a $450,000 fine.[3] The more BSL-3 facilities there are in the U.S., the more mailings of pathogens between them will occur. As the number of facilities increases, the number of shipments between them increases in a non-linear fashion. While the EA admits increases in biological agent shipments into and out of LLNL due to the presence of the proposed BSL-3 facility, the impact of the number of facilities in the U.S. since the LLNL BSL-3 was proposed in 2002 is not accounted for in the final EA. The result is that the number of shipments in 2008 and beyond into and out of the proposed facility is most likely larger, and potentially much larger, than the scope of the biological agent shipments mentioned in the EA. Hence, the risk is larger than considered in the EA.

Consideration of Terrorism Risks is Not Credible

[3] HHS Office of Inspector General, http://www.oig.hhs.gov/fraud/enforcement/administrative/cmp/cmpitems.html (last visited Mar. 7, 2008).

13. The EA posits on page 62 that "pathogenic agents studied in a BSL-3 facility . . . are already obtainable from the environment." The EA goes on to make the argument that a potential terrorist or group of terrorists would be unlikely to be interested in attacking the proposed facility or in obtaining its pathogens, such as anthrax, plague or *Coxiella burnetii*, because the terrorist(s) could "collect environmental samples from many Risk Group-2 or Risk Group-3 microorganisms and grow large quantities of them for dissemination without attacking or stealing . . . ." It concludes on page 63 that the LLNL BSL-3 would therefore not be "an attractive target" for terrorism. To reach this unsupported conclusion, the EA ignores a number of important facts.

14. Different strains of a biological agent may have widely varying virulence. Anthrax strains isolated from natural veterinary outbreaks cannot be assumed to be highly lethal for humans. Furthermore, it is not a trivial task to isolate such pathogens from nature, although it is within the ability of many Ph.D.-level microbiologists. Thus terrorists might find laboratories to be attractive sources, as they represent a source of known strains with demonstrated human virulence. For instance, the Vollum strain of anthrax was chosen for weaponization by the U.S. offensive biological weapons program in the 1950s because of its lethality (later replaced with a derivative strain, Vollum 1B). The EA Appendix C at page 9 lists experiments with the Vollum strain as among those planned for the LLNL BSL-3. Therefore, the LLNL BSL-3 might be of particular interest to a terrorist.

15. The proposed facility may perform experiments with genetically modify bioweapon agents. The EA at page 7 discusses LLNL BSL-3 experiments that will produce biological material (listed are enzymes, DNA and RNA) using infectious agents and genetically modified agents. A genetically modified agent may possess qualities uniquely interesting to a terrorist, including resistance to antibiotics, enhanced airborne transmissibility, improved durability and increased lethality. Genetically modified biological agents would be available from the LLNL BSL-3 facility but not from an infected animal or other natural source.

16. The LLNL BSL-3 is slated to contain a smorgasbord of BSL-3 organisms. This could be of interest to a terrorist, as a single break-in could yield multiple cultures, which would require separate efforts, in different parts of the world, to isolate naturally.

17. On page 59, the EA also posits that "[c]atastrophic events such as fire, explosions, and airplane crashes, normally considered as initiating events in NNSA radiological and chemical accidents, have the potential to actually reduce the consequences of microbiological material releases due to the heat produced by those events . . . ." This proposition requires more detailed analysis. Decades of work in the U.S., Soviet, and other biological weapons programs demonstrated unequivocally that microbial agents could be effectively disseminated in explosive munitions.[4] There is thus reason to believe that an explosion at the facility, either accidental or as the result of terrorist attack, could release the substantial stockpile that will be maintained there. Not only might such an event pose a threat to residents of the surrounding communities, but it might also lead to the establishment of zoonotic centers of animal infection, as many of the agents to be studied at the facility can cause animal as well as human disease. None of these potential consequences are addressed in the EA.

Consideration of the Dual Use (Offensive/Defensive) Dilemma and the Attendant Proliferation Risks is Inadequate

18. The proliferation risk embedded in BSL-3 activities being conducted at LLNL is due to its status as a highly-classified, military nuclear weapons development laboratory, a concern that is not similarly generated in biological facilities whose missions focus on unclassified civilian health initiatives and medical research. This fact alone could lead other nations to begin or escalate their own biodefense and/or biological weapons programs. There is evidence that the current trajectory of U.S. advanced biodefense activities is already raising suspicions in other nations. It is important to note that these activities are similar to those that generated the

[4] M. Wheelis, L. Rozsa, and M. Dano Eds., Deadly Cultures: Biological Weapons Since 1945, Cambridge MA: Harvard University Press (2006).

biological arms race between the U.S. and the USSR during the Cold War. The environmental, public health and potential devastation of these programs worldwide prompted President Richard Nixon to renounce offensive bioweapons programs, and for the U.S. to sign and ratify the BWC.

19. While the LLNL BSL-3 facility is proposed as part of DOE's chemical and biological weapon defense program, there always remains the possibility that the facilities could be used for offensive weapons research. Defensive biological research on select agents permitted at the LLNL BSL-3 facility will be virtually indistinguishable from offensive work in the early stages. Equally significant is the reality that, with the secrecy of the program, no one on the outside will necessarily know whether the program is strictly confined to defensive purposes. It is not clear if the DOE has in place a formal process for prior review of projects to determine if they are consistent with U.S. treaty obligations. There is an existing record of U.S. classified biodefense projects that press hard against, or perhaps transgress, treaty commitments, and situating this laboratory, with many classified projects, at a nuclear weapons facility invites suspicion that projects will not scrupulously respect treaty constraints. This creates heightened environmental, security, and proliferation risks that must be fully analyzed in the NEPA review process but are instead summarily dismissed in the EA.

20. In the EA for the proposed LLNL BSL-3 facility (Appendix C, Page 7), the DOE dismisses this issue by stating that the public can be sure the Laboratory will not conduct offensive biological weapons work because the U.S., as a party to the Biological Weapons Convention (BWC), has agreed that this nation shall not perform the actual development and production of bioweapons. However, the fact that the U.S. is a State Party to the BWC did not prevent it from undertaking classified projects in the past that many experts believed to be violations of the treaty. Moreover, in my expert opinion, there is no clear dividing line between defensive and offensive research. The advice given to President Franklin Roosevelt by his Secretary of War: "To be sure, knowledge of the offensive possibilities will necessarily be developed because no proper defense can be prepared without a thorough study of means of

offense," is as true today as it was sixty years ago.[5] In the absence of a clearly described process (including review by entities outside of and independent of DOE) for reviewing projects prior to initiation for their compliance with U.S. commitments under the BWC, the mere fact of U.S. participation in the BWC offers no confidence that its limits will be respected.

21. The BWC lacks adequate provisions for verifying treaty compliance. The treaty's failure to prevent proliferation in 1995 led to negotiations on a protocol that would establish a legally binding verification provision for the treaty. Major elements to the protocol included annual declarations, random visits and short-notice investigations. In July 2001, however, when delegates' efforts were close to producing final text, the United States withdrew its support from the verification protocol.[6] The U.S. withdrawal from negotiations on a BWC verification protocol has increased international suspicions that the U.S. is conducting or may conduct secret, prohibited bioweapons development. Those increased suspicions exacerbate the security and related proliferation risks of locating a BSL-3 facility at a highly-classified DOE nuclear weapons development laboratory and underscore the need for further review to fully address them.

22. The LLNL EA (Appendix C, Page 7) states that a 1969 decision by former President Nixon that resulted in U.S. offensive biological capabilities being destroyed and offensive-oriented research halted would prevent offensive work from being conducted at the proposed DOE biodefense facilities. However, the EA fails to note that the DOE and other agencies have resumed classified biodefense research that was stopped by the 1969 Presidential decision.[7] Thus, the extent to which the 1969 Presidential decision is still effective, if at all, is not clear and is not explained in the EA. Furthermore, the boundary between defensive and offensive work is not at all clear. The U.S. has previously done work with defensive intent that is judged by others to be prohibited by the BWC, and that it would itself consider offensive if done by another country.

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[5] Choffnes, Eileen, "Bioweapons: New labs, More Terror," Bulletin of Atomic Scientists, September/October 2002, at p. 30.

[6] Wheelis, Mark, "Back to Bioweapons?," Bulletin of Atomic Scientists, January/February 2003, at p. 42.

[7] *Id.* at 44.

23. Nor does the DOE response explain several programs (alluded to above) that may have violated the BWC that were revealed in fall 2001. For example, it was revealed that the CIA built and tested a cluster munition, modeled on a Soviet bioweapon, to spread biological agents. Another project contemplated genetically engineering pathogens to determine if they could defeat countermeasures. And a third constructed a BW production facility and used it to produce weaponized anthrax simulant, seeking signatures of such activities. In addition, the investigation into the anthrax letter attacks revealed that the United States had an ongoing program to produce dried, weaponized anthrax spores for defensive testing. How much was made is unclear, but the total production was probably in the 10s or 100s of grams of dried anthrax spores. Since a single gram of anthrax spores contains millions of lethal doses, the quantities produced might exceed levels permitted under the bioweapons treaty. Whether excess spores were stockpiled or destroyed—or whether they can even be adequately accounted for—is unknown. All of these activities were pursued with defensive intent, yet the results could also facilitate offensive BW development, and the activities were viewed with alarm by even our close allies.

24. Under the BWC's confidence building measures, agreed to in 1986, the United States made a commitment to annually declare all its biodefense projects and facilities. The above programs were not declared as required. In view of the U.S. retreat from the BWC verification protocol negotiations, the resurgence in classified biodefense work, including at the DOE, and the activities mentioned above that appear to contravene the BWC, the rationale offered in the EA about why offensive weapons work would not be conducted at LLNL is inadequate.

Need for Additional NEPA Review, Including Programmatic Analysis

25. Due to the harms posed by proliferation and security risks, it is my opinion that the DOE should prepare a Programmatic Environmental Impact Statement (PEIS) for its Chemical and Biological National Security Program (CBNP) and a Nonproliferation Impact Review, in addition to a site-specific Environment Impact Statement (EIS) for the proposed BSL-3 facility at LLNL. These reviews will determine the scope and need for a DOE high-level biodefense

program and the alternative that would cause the least environmental harm. If the DOE nuclear weapons complex is the best alternative for such a program, these review processes will thoroughly assess the potential proliferation, security and environmental harms and ways to mitigate those potential harms. This will mean that proactive plans to protect the environment, public safety and national security will be developed in advance of rather than in response to a problem, accident, crisis or catastrophe (any and all of which are foreseeable).

DOE Programmatic EIS Precedent and Public Input

26. The DOE has set an important precedent by conducting a Programmatic EIS, including a Nonproliferation Impact Review (NIR), for its Civilian Nuclear Energy Research and Development and Isotope Production Missions in the United States, Including the Role of the Fast Flux Test Facility in December 2000 and for its Stockpile Stewardship and Management in September 1996. Furthermore, Nonproliferation Analyses were conducted in the following DOE EIS or Site-Wide EIS review documents:

- Final Site-Wide Environmental Impact Statement for the Y-12 National Security Complex (September 2001);
- Final Programmatic Environmental Impact Statement for Tritium Supply and Recycling (October 1995);
- Final Environmental Impact Statement on Management of Certain Plutonium Residues and Scrub Alloy Stored at the Rocky Flats Environmental Technology Site(August 1998); and
- Final Environmental Impact Statement for the Production of Tritium in a Commercial Light Water Reactor (March 1999).

Following this precedent, the DOE's CBNP, in my opinion, should receive an equally comprehensive review.

27. I highly recommend that the Nonproliferation Impact process include public participation. This open process is critical because the question of "intent" is the key factor that

differentiates defensive from offensive biological research. The participation of citizens who live near the proposed facility and have personal concerns such as health and property values, as well as representatives from professional and nonprofit groups that specialize in public health, emergency response, sewage treatment, landfills, water, environment, science, medicine and arms control may identify heretofore unforeseen problems, cost-effective solutions and new ways to open up the process while maintaining necessary security. This scrutiny and public debate can only improve the quality of the decision and will likely result in more confidence in the final decision on the part of those most directly impacted.

Nuclear Weapons Development at LLNL Collocated with the BSL-3 is a Provocative Mix and Poses Unique Problems

28. The U.S. Nuclear Posture Review (NPR), submitted to Congress in December 2001 and made public (in part, but never wholly) on January 8, 2002, signaled a shift in U.S. nuclear weapons policy from one moored in a defensive posture to a policy that incorporates an offensive planning basis.[8] The administration's new policies abandon the concept that nuclear weapons are instruments of last resort. Instead, they integrate plans for the use of nuclear weapons with conventional weapons, thereby opening the way for the United States to use nuclear weapons for a variety of purposes against any enemy. The NPR illuminates a number of specific circumstances in which the U.S. might use nuclear weapons. These circumstances appear to sanction the use of nuclear weapons by the U.S. in situations that do not involve prior use of nuclear weapons by an enemy.

29. This shift in U.S. nuclear policy towards preemption rather than deterrence, and the choice of LLNL as the location at which to develop the first in a new series of U.S. nuclear weapons under the title of the "Reliable Replacement Warhead" program,[9] make DOE assertions

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[8] Civiak, Dr. Robert, *Soaring Cost, More Work for the Weapons labs, Less Security for the Nation: An Analysis of the Bush Administration's Nuclear Weapons Policy*, pp. 5-12, 23-24 (May 2002).

[9] The DOE announced the decision on March 2, 2007. The DOE FY2009 budget request contains up to $40 million expressly for the RRW-1 (also called WR1), which is the LLNL design.

about the purely defensive nature of its advanced biodefense work with select agents further suspect. In addition, the new U.S. nuclear posture, including the intent to replace existing warheads with the RRW, can legitimately seen as incompatible with U.S. commitments to nuclear disarmament under the Treaty on the Nonproliferation of Nuclear Weapons (commonly know as the NPT). This further erodes the confidence others might have that biodefense programs located at the same institution will respect treaty commitments under the BWC. Such suspicions make this location for a BSL-3 facility provocative and create a greater risk that other countries will pursue biological weapons research and that proliferation of bioweapons will increase around the world.

30. If the expansion of biodefense programs in the DOE does result in proliferation among other countries suspicious of the DOE biodefense program, the result will be a significant decrease in the security of the U.S. and its citizens. It will also contribute to a greatly expanded likelihood of terrorist use of bioweapons (currently very unlikely), as diversion of biological weapons from state programs to sub-state groups could short-circuit the arduous and knowledge-intensive process of terrorist bioweapon development. An open and transparent review process is necessary to insure that projects conducted at the BSL-3 facility are necessary, legal and do not contribute to proliferation. Conducting higher-level NEPA review and incorporating a non-proliferation analysis and public hearings would be a step toward promoting an appropriate level of transparency.

I declare under penalty of perjury that the foregoing is true and correct, and if called as a witness I could competently testify hereto.

Executed on (date) 7 Mar 08, (city) Davis, (state) CA.

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Professional History

AB in Biology, University of California, Berkeley, 1965

MA in Microbiology, University of California, Berkeley, 1967

PhD in Bacteriology from the University of California, Berkeley 1969
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Post-doctoral study in Biochemistry at the University of Illinois 1969-70
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On the faculty of the University of California, Davis since 1970.

Assistant Professor, 1970-1977

Associate Professor (with tenure), 1977-1982

Lecturer (with tenure), 1982-1987

Senior Lecturer (with tenure), 1987-2008

Senior Lecturer Emeritus, 2008-present

Chair, Faculty of the College of Letters and Science, 1983-84.

Acting Chair, Department of Microbiology, 1989-92.

Director, Program in Nature and Culture, 1993-94, 1999-2003

Member (since 1991) and Chair (since January 2008), Scientists Working Group on Biological and Chemical Weapons, Center for Arms Control and Nonproliferation, Washington DC (Formerly affiliated with the Federation of American Scientists)

Honors

First holder of the endowed Presidential Chair for Undergraduate Education, 1984-87.

Outstanding Faculty Advisor, Biological Sciences, 2003

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Current Research Areas

History of biological weapons

Control of biological and chemical weapons; agricultural bioterrorism; biotechnology and biological and chemical weapons control; epidemiology and field investigations of biological and chemical weapons use or accident

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"Biotechnology and Biochemical Weapons." Annual meeting of the American Public Health Association, 9 November, 2004, Washington DC.

"Military Applications of Pharmaceutical-Like Compounds." Weapons of Mass Destruction Commission ("Blix Commission"). November 12, 2004, Simmons Centre for Disarmament and Nonproliferation Research, Vancouver, Canada.

"Biotechnology, Biochemical Weapons, and the Militarization of Biology." Working paper presented to the 2nd Pugwash Workshop on Science, Ethics and Society, 10-12 September, 2004, Ajaccio, Corsica.

"Nonconsensual Manipulation of Human Physiology with Biochemical Agents." Symposium on Incapacitating Biochemical Weapons: Scientific, military, Legal and Policy Perspectives and Prospects, Geneva, Switzerland, 11 June 2005

"Agroterrorism Threats." Public Policy and Biological Threats Summer Training Program, University of California San Diego, 29 July, 2005

"The Vulnerability of US Crops to Introduced Pathogens--What Should Be Our Approach?" Annual Meting of the American Phytopathological Association, Austin, Texas, 31 July 2005.

"Anti-crop Bioterrorism: Is It a Threat?" Department of Plant Pathology, University of California Davis, October 24, 2005

"Biotechnology and Incapacitating Biochemical Weapons" American Association for the Advancement of Science annual meeting, Saint Louis, 18 February 2006

"Bioterrorism: Lessons from History." California State University Fresno, 29 September 2006.

"History of Bioterrorism and the Nature of the Threat." California State University Chico, 21 September 2007.

Invited Panel Discussions 1997-present

"Instances and Allegations of the Use of Biological Weapons," Organizer and chair of panel, Annual Meeting of the Association of Politics and the Life Sciences, Boston, 3 September 1998.

"Biological Weapons of Mass Destruction," Center for the Study of Emerging Threats, Sandia National Laboratory, 19 November 1998.

"Roundtable on Strengthening the Biological Weapons Convention" and Roundtable on Bioterrorism," Annual Meeting of the Association for Politics and the Life Sciences, Atlanta, 3-5 September 1999.

"25 Years of the Biological and Toxin Weapons Convention: Assessing Risks and Opportuniities," United Nations, Palais des Nations, Geneva, Switzerland, 27 March 2000.

"Los Riesgos de los Transgenicos," Universidad National Autonoma de Mexico, Mexico City, Mexico, 31 May 2002.

"Biowarfare: Is the Biotech Industry Fueling a New Arms Race?" BioJustice-BioDiversity 2002, Toronto, Canada, 8 June 2002.

"Incapacitating Chemical Weapons: Debating the Pros and Cons."
The Hague, Netherlands, 9 November 2005 (in conjunction with the 10th Annual Conference of States Parties to the Chemical Weapons Convention).

Invited Consultations, Reviews, Etc

World Health Organization, reviewer for the second edition of *Health Aspects of Biological and Chemical Weapons*, 1999-2002.

US Department of Energy. Member, Study Section on Chemical and Biological Nonproliferation, Washington DC, 29-30 June, 1999.

International Committee of the Red Cross. Consultant, SIrUS Project (Towards a determination of which weapons cause "superfluous injury or unnecessary suffering"), 1997-1998.

Government Accountability Office. Topic: Non-Lethal Weapons. 13 November 2003, Washington, DC.

Verification Research, Training and Information Centre (VERTIC). Workshop on Strengthening Tools and Mechanisms for Verifying Biological Weapons Compliance. 13-14 May, 2004, London, UK.

United Nations Monitoring, Verification and Inspection Commission (UNMOVIC). Member of an expert panel invited to recommend changes in UNMOVIC monitoring activities in Iraq, 3-5 November, 2004, New York City.

Government Accountability Office. Topic: Agroterrorism. 3 May, 2004, Washington, DC.

26th Workshop of the Pugwash Study Group on the Implementation of the Chemical and Biological Weapons Conventions, Noordwijk, Netherlands, 17-18 March 2007 (invited participant)

IUPAC/OPCW International Workshop on the Impact of Advances in Science and Technology on the Chemical Weapons Convention, Zagreb, Croatia, 22-25 April, 2007 (invited participant)

EXHIBIT 4

DOE/EA-1442R

National Nuclear Security Administration

Draft Revised Environmental Assessment for The Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California

Issued: December 2002

Revised: March 2007

Department of Energy
National Nuclear Security Administration
Livermore Site Office

vehicle miles (161 million kilometers). The number of hazardous materials shipments is about 800,000 per day with at least 10,000 involving waste hazardous materials identified generally as medical wastes and various other hazardous materials. For the hazardous materials category that includes infectious substances, about 80 percent of these shipments are carried by truck with the remainder carried by rail (DOT 1998). There are an estimated 4,300 non-hospital waste generating facilities (laboratories) that are potential generators of medical waste and other kinds of infectious substances including diagnostics specimens. These facilities generate 73,037 tons per year of infectious medical waste and ship about 200 tons (181,000 kg) per day (DOT 1998). Information extracted from the DOT Hazardous Materials Information System (HMIS) database (DOT 2001b) on infectious substances transportation from 1995 to 1999 show that infectious substance incidents are too few to even be ranked. There is, however, an apparent national increase in overall hazardous materials incidents, which rose from 14,700 in 1995 to 17,069 in 1999.

LLNL has never had a biological-material transportation accident (PC 2002). However, in September 2005, LLNL sent shipments of vials containing select agent material to two offsite laboratories. Upon receipt, it was determined that the inner packaging of these shipments violated DOT packaging requirements and that the labels were missing important information. No illnesses or injuries occurred. The incident was examined and reviewed by the CDC and the DOT. In addition, an Incident Analysis Committee was empanelled by the LLNL to review the incident conduct to determine the root causes. During the review period, all select agent transfers were suspended at LLNL.

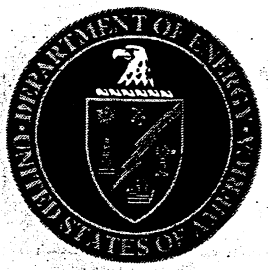
At the end of the review, the CDC, DOT, and NNSA determined that corrective actions were implemented successfully. Subsequently, LLNL's permit to work with select agents and toxins was renewed by CDC in 2006 for 3 years and transfers were allowed to resume.

Accidents due to transportation of microorganisms are not expected to increase due to the Proposed Action. The addition of milliliter-quantity samples shipped to and from the BSL-3 facility through federal or by commercial or private courier would not be expected to change the overall incidence of risk of transportation accidents. Samples could consist of cells in media contained within DOT-certified packages. The consequences of such accidents would be anticipated to be minor, based on the historical data.

4.3 Analysis of Threat of Terrorist Activity

Environmental reviews prepared under CEQ implementing regulations and DOE NEPA regulations require a presentation of the environmental impacts of the proposed action and the alternatives in comparative form, thus defining the issues and providing a clear basis for choice among options by the decision-maker. With regard to intentional malicious acts, the assessment should compare potential impacts of acts by a terrorist that could derive from the proposed action, or that could occur with significantly greater probability as a result of the proposed action, to the potential impacts from those that could already occur if research with pathogenic agents requiring BSL-3 level containment is not conducted at LLNL (the "No Action" alternative).

EXHIBIT 5



DOE/EA-1442

Environmental Assessment for The Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California

December 2002

Department of Energy
National Nuclear Security Administration
Oakland Operations Office

EXECUTIVE SUMMARY

The Department of Energy (DOE), National Nuclear Security Administration (NNSA), has responsibility for national programs to reduce and counter threats from weapons of mass destruction including nuclear, chemical, and biological weapons (bioweapons). NNSA's bioscience work at Lawrence Livermore National Laboratory (LLNL) in support of these missions requires work with infectious agents, including those historically used for bioweapons. The laboratory's pioneering work on biological agent (bioagent) detection and counter-terrorism technologies, and basic research understanding of emerging and re-emerging natural diseases are key elements of the LLNL efforts to support the NNSA mission. As a result, the need to conduct research with infective agents in a secure environment at LLNL and within NNSA is growing rapidly.

DOE does not currently operate any microbiological laboratory facility beyond Biosafety Level (BSL)-2. Much of the proposed work must be performed with BSL-3 containment and protection. BSL-3 facilities provide for environmentally safe and physically secure manipulation and storage of infectious microorganisms, many of which are potential bioweapon agents. NNSA's BSL-3 work would require efficient high-quality sample processing, and, for scientific and security reasons, assurance of sample security and integrity. These requirements also necessitate that cross-contamination and degradation of samples be minimized by reducing excessive handling and transportation. The few offsite commercial or governmental BSL-3 facilities currently available are often heavily committed to other projects or tailored to work with specific types of microorganisms. In order to more effectively utilize and capitalize on LLNL's existing onsite facilities, expertise, and capabilities, and ensure the necessary quality, integrity, and security of microbiological work, NNSA needs BSL-3 laboratory capability at LLNL.

The Proposed Action and alternatives differ mainly in how the facility would be constructed. In all of the alternatives, the BSL-3 facility would be designed and operated in accordance with guidance for BSL-3 laboratories established by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). Physical security would be implemented commensurate with the level of work being performed within the facility. No radiological, high explosives, or propellant material would be used or stored in the proposed BSL-3 facility. The proposed facility would have the unique capability within DOE/NNSA to perform aerosol studies to include challenges of rodents using infectious agents or biologically derived toxins (biotoxins). Sample shipments would be received only in compliance with all established shipping guidelines and requirements. The samples would be stored in the BSL-3 laboratory within a locked labeled freezer or refrigerator according to the needs of the sample for preservation. Biological wastes would be disposed of in accordance with CDC and NIH guidance, and other applicable federal, state, and local regulations.

The Proposed Action is to assemble on-site an approximately 1,500 ft^2, one-story permanent prefabricated BSL-3 laboratory facility which would have three individual BSL-3 laboratory rooms (one capable of handling rodents), a mechanical room, clothes-change and shower rooms, and small storage space. The building footprint would take less than one-quarter acre. It is estimated that the operational design life of the proposed building would be at least 30 years.

operation at the BSL-3 level, and would not be easy to retrofit to meet these criteria. Also, as noted earlier, all biological work conducted at LLNL must be reviewed by the Laboratory Biosafety Operations Committee (LBOC) and, when involving pathogenic organisms specifically, reviewed and approved by the IBC. Work that is not in conformance with federal regulations, CDC/NIH Guidelines, DOE Orders, and LLNL directives cannot be performed because it would not be approved by the IBC and would not be in conformance with provisions of the U.C. contract with DOE.

The term "weaponization" in reference to biological agents can be broadly defined as "the design, and production and storage in large quantity, of biological agents and their delivery systems for military purposes." This is not being done at LLNL, and is not a part of a DOE proposal. Aerosol challenges do not imply "weaponization". An aerosol challenge is the method used to test a rodent by inhalation. The route of pathogen exposure affects the timing for onset of symptoms and it is the inhalation pathway that is one of the quickest. Aerosol challenge allows for testing of detection assays, treatment regimens, and medical intervention approaches as a consequence of inhalation exposures to pathogens. Nebulizers used for challenging test animals are frequently employed in private industry, including in the research and development of cosmetic products. The research proposed for the BSL-3 facility would involve growing and culturing agents, and in some cases challenging rodents by means of administering agents with a nebulizer. Again, no technology is being proposed, developed, or adapted at LLNL for the purpose of "weaponizing" agents.

4. Compliance with Biological Weapons Convention

A commentor expressed concern that the proposed work would undermine the Biological Weapons Convention and be viewed with suspicion by the world community. Additionally, the commentor remarked that the draft EA gives no indication of how BWC compliance would be instituted. Several commentors were of the opinion that the draft EA does not provide a process to guarantee public scrutiny of the LLNL biosafety committee deliberations and decision making.

Response

U.S. participation in the Biological Weapons Convention is discussed under topic 3 above.

The proposed BSL-3 facility would be operated according to all guidance and requirements established by such agencies as the CDC, NIH, USDA, DOE and LLNL. Specific guidance references are detailed in Section 2.1.2 of this EA. NIH guidelines require that an IBC be appointed by an institution to provide local and institutional oversight and approval of potentially hazardous lines of biological research (NIH 2001). Section IV-B-2 of the NIH guidelines establishes procedures that the IBC shall follow in its role of review and approval responsibility. These guidelines include review and approval of applications, proposals, and activities; and making available to the public, upon request, all IBC meeting minutes and any documents submitted to or received from funding agencies that those agencies must make available to the public. As detailed in this EA and in the NIH guidelines, at least two members of the IBC are not affiliated with LLNL and they represent the interest of the surrounding community with respect to health and protection of the environment. These IBC members may

be officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns of the community. Since the IBC is ultimately responsible for ensuring that research conducted at, or sponsored by, LLNL is in compliance with applicable guidelines or regulations, this ensures that the public will be involved in approval of BSL-3 research and review of safety and compliance protocol as it does now for certain BSL-2-level projects. It is possible that some specific project information will be subject to DOE security and classification restrictions, and will consequently not be made available to the public. All proposed microbiological research projects at LLNL, even projects with classified portions, will undergo review and approval by the IBC.

The IBC was established at LLNL in 1991 to ensure compliance with recognized guidelines and regulations concerning research with recombinant DNA or human, animal, and plant pathogens. In 1998, the IBC registered LLNL under the Laboratory Registration and Select Agent Transfer Program of CDC. As currently practiced at LLNL, the IBC must approve all research in the cited subject areas prior to commencement.

5. Public Health and Safety, and Worker Safety Issues

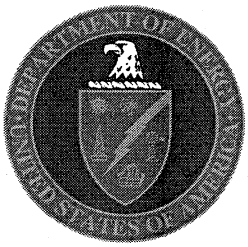
Comments regarding the issue of public health and safety ranged from general opposition to a BSL-3 facility at LLNL to specific concerns about the potential for accidents and the implementation of procedural safeguards. One commentor remarked that there was no evidence that LLNL conducted a preliminary hazards analysis for the proposed facility and another commentor stated that it was inappropriate to allow biological warfare agent research so close to a major population center. Commentors also expressed the opinion that anticipated work with genetically modified organisms would pose unique or unknown risks to the general public, emergency personnel, and regional medical workers. Commentors expressed concern about how LLNL would respond in the event of an accident at the BSL-3 and how the lab would notify the public and provide information on emergency response actions during an accident.

One commentor remarked that the Draft EA failed to address the effect that a release or exposure could have on the way a region functions. The commentor cited the anthrax attacks of 2001 as an example of the difficulties of determining the nature and extent of a hazard and the potential for entire facilities to close down, despite a relatively small number of casualties. One commentor stated an opinion that the immunization status of laboratory workers represents critical information that should be available to all employees of LLNL and residents of the area.

Response

A Preliminary Authorization Basis Document (analogous to a preliminary hazard analysis) would be completed and approved by NNSA prior to the facility being constructed. A Final Authorization Basis Document (analogous to a final hazard analysis) will be completed and approved by NNSA prior to the facility becoming operational. As for emergency response, the scope and extent of emergency planning and preparedness at LLNL are based on, and commensurate with, the hazards and potential consequences associated with a facility and its operation. The Laboratory uses an emergency management system (known as the Incident Command System) that is capable of responding to and mitigating the consequences resulting

EXHIBIT 6



National Nuclear Security Administration

DOE/EA-1442R

Final Revised Environmental Assessment for The Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California

Issued: December 2002

Revised: January 2008

Department of Energy
National Nuclear Security Administration
Livermore Site Office

FORWARD

The National Nuclear Security Administration (NNSA) of the Department of Energy (DOE) has responsibility for national programs to reduce and counter threats from weapons of mass destruction including nuclear, chemical, and biological weapons (bioweapons). NNSA's bioscience work at Lawrence Livermore National Laboratory (LLNL) in support of these missions requires work with infectious agents, including those historically used for bioweapons. Much of the proposed work must be performed with Biosafety Level 3 (BSL-3) containment and protection. Accordingly, NNSA proposed to construct and operate a BSL-3 facility at LLNL to meet the NNSA mission to "develop, demonstrate and deliver technologies and systems to improve domestic defense capabilities and, ultimately, to save lives in the event of a chemical or biological attack." A Environmental Assessment (EA) and a Finding of No Significant Impact for the proposed BSL-3 facility was issued in December 2002 (BSL-3 EA, DOE/EA-1442), and construction of the facility began.

On September 16, 2003, Tri-Valley CARES filed a lawsuit in the federal district court in San Francisco challenging the adequacy of the EA for the proposed BSL-3 facility. On September 10, 2004, the district court found the EA to be adequate. On November 8, 2004, Tri-Valley CARES filed a notice of appeal with the Ninth Circuit Court of Appeals. On October 16, 2006, the appellate court issued a memorandum opinion (D.C No CV-03-03926-SBA). In light of the Ninth Circuit's recent ruling in an unrelated case, the court remanded the matter for DOE to consider whether the threat of potential terrorist activity necessitates the preparation of an environmental impact statement. DOE issued interim guidance on how to address intentional destructive acts in NEPA documents (DOE 2006) as a result of the Ninth Circuit's decision.

In response to this ruling and the guidance, NNSA has revised the 2002 EA to consider the potential impacts of terrorist activity. NNSA has limited the changes to the document in matters not related to the terrorist analysis; however, some updates were necessary. The Appendices to the original EA were not revised. Since this EA, NNSA has issued the *Final Site-wide Environmental Impact Statement for Continued Operation of Lawrence Livermore National Laboratory and Supplemental Stockpile Stewardship and Management Programmatic Environmental Impact Statement* (SWEIS, DOE/EIS-0348, DOE/EIS-0236-S3, DOE 2005). Background information in this EA has been updated to reflect more current information in the SWEIS if the updated information is pertinent to NNSA's determination of the potential effects of the proposed action on human health or the environment. Also since 2002, the proposed building has been constructed and all facility-related equipment installed. As such, NNSA acknowledges that the impacts related to construction that are discussed in this document have already occurred; these impacts were analyzed in the 2002 EA and considered in issuing the Finding of No Significant Impact (FONSI). Other minor changes have been made if guiding regulations or DOE policies have been updated since 2002. Change bars (a vertical line in the margin next to the text which was changed) indicate significant changes in the document made since the revised draft was made available for public comment in March, 2007.

EXECUTIVE SUMMARY

The National Nuclear Security Administration (NNSA) of the Department of Energy (DOE) has responsibility for national programs to reduce and counter threats from weapons of mass destruction including nuclear, chemical, and biological weapons (bioweapons). NNSA's bioscience work at Lawrence Livermore National Laboratory (LLNL) in support of these missions requires work with infectious agents, including those historically used for bioweapons. The laboratory's pioneering work on biological agent (bioagent) detection and counter-terrorism technologies, and basic research understanding of emerging and re-emerging natural diseases are key elements of the LLNL efforts to support the NNSA mission. As a result, the need to conduct research with infective agents in a secure environment at LLNL and within NNSA is growing rapidly.

DOE does not currently operate any microbiological laboratory facility above Biosafety Level 2 (BSL-2). Much of the proposed work must be performed with Biosafety Level 3 (BSL-3) containment and protection. BSL-3 facilities provide for environmentally safe and physically secure manipulation and storage of infectious microorganisms, many of which are potential bioweapon agents. NNSA's BSL-3 work would require efficient high-quality sample processing, and, for scientific and security reasons, assurance of sample security and integrity. These requirements also necessitate that cross-contamination and degradation of samples be minimized by reducing excessive handling and transportation. Commercial or governmental BSL-3 facilities currently available are often heavily committed to other projects or tailored to work with specific types of microorganisms. In order to more effectively utilize and capitalize on LLNL's existing onsite facilities, expertise, and capabilities, and ensure the necessary quality, integrity, and security of microbiological work, NNSA needs BSL-3 laboratory capability at LLNL.

The Proposed Action and alternatives differ mainly in how the facility would be constructed. In all but the No-Action alternative, the BSL-3 facility would be designed and operated in accordance with guidance for BSL-3 laboratories established by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). Physical security would be implemented commensurate with the level of work being performed within the facility. No radiological, high explosives, or propellant material would be used or stored in the proposed BSL-3 facility. The proposed facility would have the unique capability within DOE to perform aerosol studies to include challenges of rodents using infectious agents or biologically derived toxins (biotoxins). Sample shipments would be received only in compliance with all established shipping guidelines and requirements. The samples would be stored in the BSL-3 laboratory within a locked labeled freezer or refrigerator according to the needs of the sample for preservation. Biological wastes would be disposed of in accordance with CDC and NIH guidance, and other applicable federal, state, and local regulations.

The Proposed Action is to assemble on-site an approximately 1,500 ft^2, one-story permanent prefabricated BSL-3 laboratory facility which would have three individual BSL-3 laboratory rooms (one capable of handling rodents), a mechanical room, clothes-change and shower rooms, and small storage space. The building footprint would take less than one-quarter acre. It is estimated that the operational design life of the proposed building would be at least 30 years.

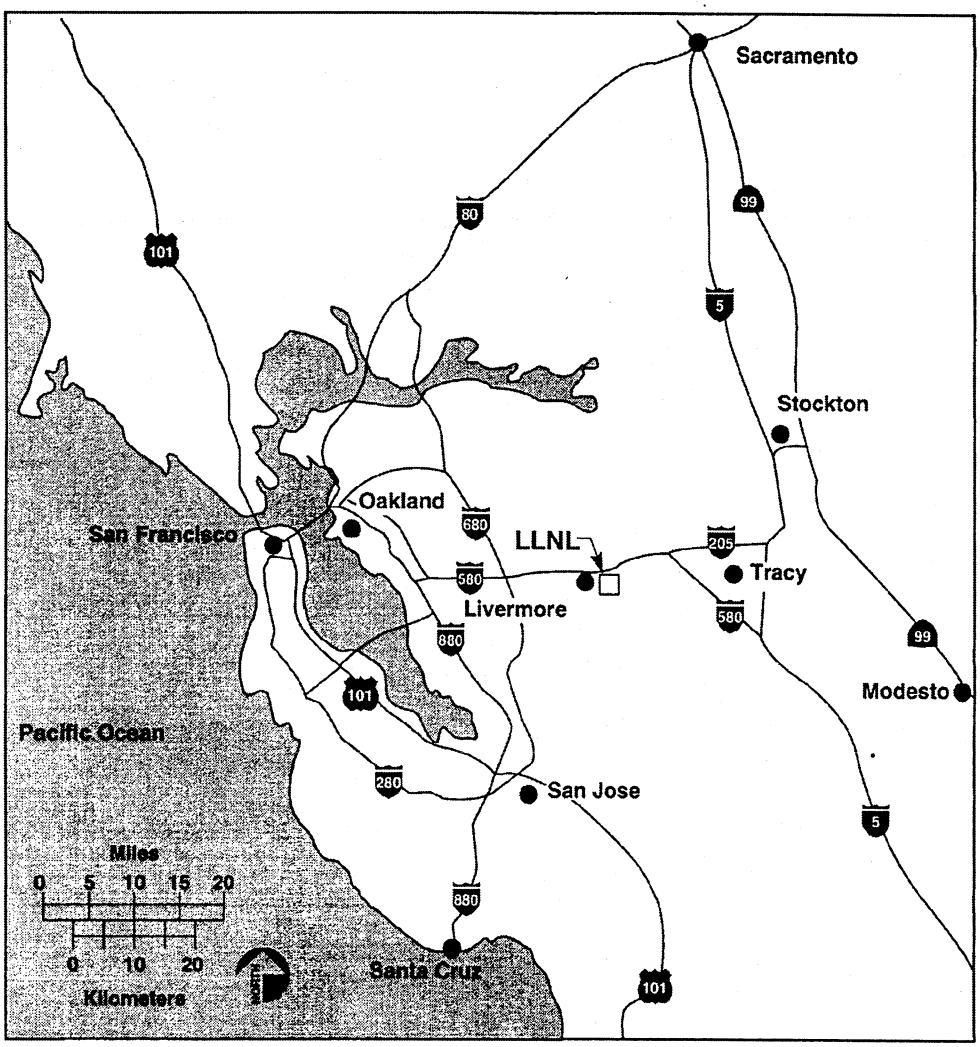


Figure 1-1. Location of Lawrence Livermore National Laboratory (LLNL)

1.2 BACKGROUND

The LLNL Livermore site lies just outside the boundary of Livermore, California. It occupies a total area of approximately 1.3 sq miles (821 acres), and is about 40 miles east of San Francisco at the southeast end of the Livermore Valley in southern Alameda County, California. The City of Livermore's central business district is located about 3 miles to the west. Figure 1-1 and Figure 1-2 show the regional location of the LLNL Livermore site and its location with respect to the City of Livermore. Lawrence Livermore National Laboratory (LLNL) is a U.S. Department of Energy national laboratory operated by the University of California (UC). Since the publication of this EA, a new M&O contractor for LLNL has been selected, Lawrence Livermore National Security, LLC (LLNS). LLNL was founded in September 1952 as a second nuclear weapons design laboratory to promote innovation in the design of our nation's nuclear stockpile through creative science and engineering. LLNL has also become one of the world's premier scientific centers, where cutting-edge science and engineering in the interest of national security

biological attack. The threat presented by terrorists and rogue nations to the American people and our allies, including military personnel, amplifies the need for threat reduction research. Current work at LLNL in bioscience research is limited to BSL-2. Pending and future work in support of the DOE, NNSA, and DHS national security missions requires specialized facilities to safely and securely handle and store infectious organisms beyond that which can be provided by BSL-2. DOE does not currently have under its administrative control within the DOE complex any microbiological laboratory facility capability beyond BSL-2, but BSL-3 facilities are proposed both at LLNL (as outlined in this EA) and at Los Alamos National Laboratory (LANL) (DOE 2002b).

Additional information regarding the DOE and NNSA mission areas of work conducted at LLNL is presented in the *Final Environmental Impact Statement and Environmental Impact Report for Continued Operations of Lawrence Livermore National Laboratory and Sandia National Laboratories, Livermore, August 1992* (DOE/EIS-0157) (DOE 1992), its associated Supplement Analysis (SA) (DOE 1999), and the *Final Site-wide Environmental Impact Statement for Continued Operation of Lawrence Livermore National Laboratory and Supplemental Stockpile Stewardship and Management Programmatic Environmental Impact Statement* (SWEIS, DOE/EIS-0348, DOE/EIS-0236-S3, DOE 2005).

1.3 PURPOSE AND NEED FOR AGENCY ACTION

DOE conducts bioscience work in support of its biology and biotechnology research programs, work for other agencies, and work in support of CBNP. The NNSA CBNP mission is to "develop, demonstrate and deliver technologies and systems to improve domestic defense capabilities and, ultimately, to save lives in the event of a chemical or biological attack."

In order to meet these mission requirements, it is necessary to expand some existing capabilities to test the understanding and effectiveness of research on infectious agents and biotoxins, particularly those associated with potential bioweapons threats. Efficient execution of the NNSA mission therefore, also requires the capability to handle operations involving small-animal (rodent) challenges of bioagents (and possibly biotoxins) and the ability to produce small amounts of biological material (enzymes, DNA, ribonucleic acid[6] [RNA], etc.) using infectious agents and genetically modified agents under conditions that would require management of the facility at the BSL-3 level.

This capability does not currently reside within DOE/NNSA facilities, but some of the research is carried out for the LLNL Nonproliferation, Arms Control, and International Security (NAI) Directorate primarily by the BBRP using external (private-sector and University) laboratories to conduct the BSL-3 level components of the research. The nature of BSL-3 work requires efficient sample processing, handling of a variety of organisms concurrently, and assurance of sample security and integrity. NNSA's mission requirements for sample integrity necessitates that the chances of cross-contamination and degradation of samples be minimized by reducing excessive handling and transportation. The several key off-site BSL-3 facilities that conduct work for LLNL in support of NNSA, are often heavily committed to other projects or tailored to

[6] Ribonucleic acid or RNA is a generic term for a group of natural polymers present in all living cells directly involved with protein synthesis.

work with microorganisms not of specific interest to NNSA. This has especially become an issue since September 11, 2001. Because of this these laboratories are unlikely to be able to provide the quick response that may be necessary to support the NNSA need.

An on-site BSL-3 facility would provide safe and secure manipulation and storage of infectious microorganisms at a time when these issues are imperative to national security. In order to more effectively utilize and capitalize on existing onsite facilities and capabilities at LLNL, including informatics and DNA sequencing capability, and to ensure the quality, timeliness, integrity and security of microbiological work, NNSA needs BSL-3 laboratory capability within the boundaries of this national laboratory.

1.4 PUBLIC INVOLVEMENT

The Draft EA was originally made available for public comment from July 24 through August 23, 2002. The comment period was extended through September 7, 2002.

The revised document was made available for a 30 day comment period beginning April 11 and ending May 11, 2007. No comments received were excluded from the record. All comments were accepted even if they were received after the 30 day period.

1.5 COMMENT SUMMARIES AND NNSA RESPONSES

The full text of the comments received by NNSA on the Revised Draft EA by stakeholders and members of the public are included in Appendix C-2 of this EA. Where comments were duplicated, as in the presentation of form-type letters, only one is shown in its entirety. Many of the topics generated from public responses are of broad interest or concern and were categorized into twelve general issues which comprise the twelve sections in Appendix C-1. Comments and concerns voiced by the commentors were addressed through changes made to the document text to the extent practicable. Some commenters raised issues that are not pertinent to the NEPA review. These were also addressed to the extent practicable. The following general issues are discussed in the appendix:

1. NEPA Compliance: Documentation/Review Level
2. Safety of Laboratory Operations
3. Defensive vs. Offensive-oriented Research
4. Compliance with the Biological Weapons Convention
5. Public Health and Safety, and Worker Safety Issues
6. Accident Analysis
7. Threat of Terrorist Attack/Sabotage
8. Transportation Safety
9. Purpose and Need
10. Adequacy of Alternatives Analysis
11. Waste Disposal
12. Timeline for the BSL-3 Facility
13. Oversight
14. Public Comment Period and Public Hearings

continuous quarantine status, protecting personnel and preventing contact with the other rodents in the cage rack. A maximum of 100 rodents, mainly mice (some rats and possibly guinea pigs), would be used at any one time. Once a rodent would be used in testing it would never leave the cage except for cage-cleaning and inspection which would occur only in the confines of the BSCs. Once removed from a cage the rodents would only be placed back into a clean cage. The dirty cage and its contents would be autoclaved[13] prior to reuse. All rodents used would be supplied by the already-existing rodent quarantine facility located and operated in an adjacent building. The cage rack would be restrained from toppling over by resisting about 1g of lateral acceleration. Cage latches have been tested to 2g's of pull force.

Some rodents would be exposed to infectious agents in the BSC through inhalation via a device known as a collision nebulizer. This device creates aerosol particles of known size (depending upon the specific nozzle used) to which rodents would be exposed through a nose-piece. The nebulizer consists of a 32-ounce Pyrex™ glass liquid storage container with a "T-shaped" stainless steel aerosol jetting-device operated by compressed air. The device would only be used in the BSC and would be chemically disinfected in place after use. Once exposed, the rodent would (while still in the BSC) be placed directly into a clean cage and placed back into the ventilated cage rack for observation.

Physical security of the facility building would be implemented commensurate with the level of work being performed. The facility safeguards would be based upon a security analysis conducted during the project planning stage. As in all facilities managed at LLNL, security in the proposed facility would be maintained by limiting access to only authorized DOE-badged personnel. Employee qualifications and training requirements are described in CDC-NIH guidelines (CDC 1999) along with a discussion of appropriate management of security concerns.

Fire suppression for the BSL-3 facility would be provided by a standard wet-pipe fire sprinkler system. Water flow alarms would be connected to LLNL's fire alarm monitoring station so that designated responders would be notified. Water used for fire suppression that might become pooled on the building floor would be discharged from the floor drains to a retention tank system, for containment, characterization, and disinfection as needed, prior to discharge to the sanitary sewer system.

Two HEPA filter banks in series in the building exhaust system would filter all room air one-time-through and provide secondary filtration for exit air from the BSCs. Filter banks could be switched or alternated to permit disinfection and filter replacement. Routine maintenance of the filter banks would be conducted by certified technicians, including replacement of the filters. Replaced filters would be chemically sterilized prior to disposal. There would be only one electrical room with access for maintenance from the exterior of the building. The BSL-3 facility would employ lightning protection designed to meet the requirements of the National Fire Protection Association (NFPA 1997 and 2000). Entry of personnel into the BSL-3 laboratories would be through the change rooms which would serve as self-closing double-door access.

[13] An autoclave is an apparatus using superheated steam under pressure to kill or sterilize microorganisms

(42 CFR 72). The CDC is the supporting governmental agency under the HHS responsible for the management of the Laboratory Registration/Select Agent Transfer (LR/SAT) Program and would be the main point of contact for LLNL's Facility Responsible Official. LLNL would be required in accordance with the Integrated Safety Management System (ISMS) to participate in and follow the requirements of the CDC LR/SAT Program for handling of select agents[14] and must follow the provisions that apply to the six LR/SAT components as appropriate, which include (1) the list of approximately 40 "select agents" that are "viruses, bacteria, rickettsia, fungi, and toxins whose transfer in the U.S. is controlled due to their capacity for causing substantial harm to human health;" (2) registration of the facilities; (3) filing of approved transfer form; (4) verification using audits, quality control, and accountability mechanisms; (5) agent disposal requirements; and (6) research and clinical exemptions (42 CFR 72). No select agents would be handled in the proposed BSL-3 laboratories without first obtaining IBC approval in accordance with ISMS and secondly prior registration and approval from CDC. Microorganisms that are not select agents would also be used in the BSL-3 laboratories but would still be handled according to CDC and NIH guidances and requirements. Operation of the proposed facility would also involve handling of microorganisms that are regulated by the U.S. Department of Agriculture (USDA) and require BSL-3 containment.

Microorganisms expected to be cultured (i.e., viable organisms) at the BSL-3 facility in the near term would be, but not limited to, the select agents *Bacillus anthracis*, *Yersinia pestis*, *Clostridium botulinum*, *Coccidioides immitis, Brucella spp., Francisella tularensis, and Rickettsia spp.* (see Appendix A). The facility may be used to handle small amounts of biotoxins which are generally handled at the biosafety level established for the microorganisms that produce them. The CDC and NIH guidances and requirements also extend to handling genetically modified microorganisms. All research in microbiology laboratories that involves altering microbial genomes follows standard procedures approved by NIH (NIH 2001). It is possible that the facility would receive genetically altered microorganisms. Before any infectious microorganisms would be handled in the BSL-3 laboratories, the IBC and the researcher, in accordance with CDC guidance, would perform a risk analysis. LLNL occupational medicine and the local medical community would be informed of the microorganisms to be handled in the BSL-3 laboratories and would be aware of the methods of identification and control of associated diseases.

All work with infectious microorganisms in the proposed facility must be approved and authorized by LLNL management in strict accordance with the following:

- Biological Weapons Convention Treaty (BWC 1972) permits defensive research for the purpose of developing vaccines and protective equipment.
- Appendix G of the UC Contract with DOE specifies, among other things, Work Smart Standards, which include adopted standards from CDC (42 CFR 73), NIH (2001), and the U.S. Occupational Safety and Health Administration (OSHA) (29 CFR 1910, 29 CFR 1926).

[14] Select agents are biological agents of human disease whose transfer or receipt requires a facility to be registered with the CDC under 42 CFR Part 72.6; select agents have historically been associated with weaponizing efforts.

3 laboratory areas would be informed of what other workers would be handling so that appropriate staging of work could occur. Open cultures would only be handled in BSCs. BSCs would be at negative pressure with respect to the room and the rest of the building. Airflow would always be directed away from the worker and into the BSC. Workers would be offered appropriate immunizations for the microorganisms being handled. They would also be tested for normal immunocompetancy[16], and would have medical treatment readily available in the event of an accidental exposure.

No radiological material would be used or stored in the BSL-3 facility. A pest program would be in place to control vector populations.

One of the three BSL-3 laboratories would have rodent handling capability (<100 rodents). The rodents (mice, rats, and possibly guinea pigs) would be in the BSL-3 facility only when part of a research study. These rodents would be cared for in accordance with federal regulations and guidelines. LLNL adopted the requirements of the Animal Welfare Act of 1968 (7 USC 2131-2157, as amended) and voluntarily adheres to the guidelines for the use of vertebrate animals in research established by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. These requirements are administered by the LLNL Associate Director for the BBRP and are implemented by the LLNL Institutional Animal Care and Use Committee (IACUC).

Rodents would be held in quarantine in another Building 360 Complex laboratory for at least 30 days prior to use in a BSL-3 laboratory. They would be maintained in enclosed cages that would individually be connected to the building exhaust air duct. All rodent studies would occur only in the BSL-3 BSCs. Rodents are routinely transferred from dirty to clean cages in the BSCs. Used cages would be closed, autoclaved without dumping the litter, then further cleaned and disinfected prior to reuse. Rodent studies could involve intravenous injections and therefore the laboratories would have sharps, sharps containers, and a "needlestick" program that would be developed at the outset and would focus on ensuring workers do not accidentally inject themselves (autoinjection). All rodents brought into the proposed facility would be euthanized for the purpose of post-mortem medical examination (necropsy). All necropsied rodents and rodent tissues would be sterilized in a tissue digester located in the rodent BSL-3 laboratory.

The BSL-3 facility would not be a large-scale research or production facility, which is defined as working with greater than 10 liters of culture quantities (NIH 2001). Quantities of each cultured microorganism would be further limited by experiment-specific procedures under IBC approval. Less than 1 liter of cultured microorganisms in their stationary growth phase (maximum cell density of about 10^8 cells per ml) would be the maximum quantity handled in any BSL laboratory at any point in time. This 1-liter quantity would only be removed from the BSC in 250 ml double-contained plastic containers with safety-caps. No open cultures (where the free liquid surface is exposed directly to the ambient air) would be allowed outside of the BSC.

Seed cultures or samples would be provided by commercial suppliers, research collaborators, or other parties associated with the LLNL projects. These may contain either previously identified or unidentified organisms. Identification provides diagnostic, reference, or verification of

[16] Immunocompetancy is the ability to have normal immunity from infection.

strains[17] of microorganisms present. Diagnostic and reference strains, which may include the geographic source of the sample, contribute to the understanding of the microorganism's original source and ability to cause disease. Rapid, accurate reference or verification of strains improves containment of infection through early and effective medical intervention, potentially limiting the progress of illness for those exposed to pathogens, determination of antibiotic resistance, and contamination or infection of others.

The CDC would periodically inspect the facility over the life-time of its operation. The inspections would be performed by CDC staff or its contractors.

Sample Arrival at the LLNL BSL-3 Facility for Processing: Sample shipments would only be received at the BSL-3 facility operating within the parameters specified in all established guidelines and requirements. If the samples would be select agents, they would only be accepted when the CDC Form 2 has been completed per regulations, the registration verified, and the requesting facility responsible official notified in advance of shipment according to CDC registration requirements. Biological materials or infectious agents could only be shipped to LLNL by commercial package delivery services, the U.S. Postal Service (USPS), other authorized entity, or delivered to the receiving area from an origination point within LLNL by a designated LLNL employee acting as a courier (39 CFR 111; 42 CFR 72; 49 CFR 171-178). Generally, shipment sample sizes would be small; a typical sample would consist of about a milliliter of culture media (agar solid) with live cells (a milliliter is about equal to one-fifth of a teaspoon in volume). Smaller samples could be shipped that would be microliters in size; the maximum probable sample size would be 15 milliliters.

The protocol for receiving and handling of samples (such as soil) would be worked out prior to receipt and reviewed and approved by the IBC. Receipt of the select agents must be acknowledged electronically by the requesting facility responsible official within 36 hours of receipt and a paper copy or facsimile transmission of receipt must be provided to the transferor within 3 business days of receipt. Upon this acknowledgement, the transferor would be required to provide to the LLNL-requesting-facility responsible official a completed paper or facsimile transmission copy of the CDC form within 24 hours to the registering entity (holding that facility's registration), in accordance with §72.6(c)(2) (42 CFR 72) for filing in a centralized repository.

All incoming packages (regardless of origination point) containing infectious agents would have to have been packaged in DOT-approved packages (42 CFR 72) (see Figure 2-6). These packages would be about 6 to 8 inches (15 to 20 cm) in height and about 3-4 inches (8 to 10 cm) in cylinder diameter. All shipping containers would be made of plastic and the samples would be double- or triple-contained. Transportation and interstate shipment of biomedical materials and import of select agents would be subject to the requirements of the U.S. Public Health Service Foreign Quarantine (42 CFR 71), the Public Health Service, and DOT regulations. Additionally, the U.S. Department of Agriculture regulates the importation and interstate shipment of animal or plant pathogens (7 CFR 330 and 9 CFR 92). Strict chain-of-custody procedures for samples arriving at the LLNL receiving site would be followed.

[17] Strains are the very lowest taxonomic (naming organisms) designation; it generally means cells descended from a single isolate which have not mutated significantly from the exact DNA sequence of that original single cell.

buffer zone of the LLNL Livermore Site in the mid-1990s. Additionally, the Federally threatened California red-legged frog (*Rana aurora draytonii*) has been found in the Arroyo Los Positas (along the northern buffer zone). A BA was completed in 1997 and amended in 1998 to account for potential impacts to the frog from routine maintenance activities at the LLNL site. In 2001, a narrow strip along the northern and eastern edges of the site were designated as a portion of the federal critical habitat for the frog. The proposed BSL-3 facility would not be located in or near these natural resource-sensitive areas.

Although not usually considered as such, soils are also an ecological resource (Burden and Sims 1999). Soils are known to naturally contain a diversity of numbers and types of microorganisms. The range is substantial as it depends upon the environmental conditions, which dictate the bacteria and fungi microflora (plant microorganisms) that can survive. Infectious microorganisms can also be found naturally in soils. Some of these may be handled in the proposed BSL-3 laboratories (e.g., *Bacillus spp.* and *Clostridium spp.*).

3.3.2 Human Health

In 2000 there were approximately 1.3 million people living in Alameda County (HRSA 2000), in which Livermore is located, and about 6.9 million people living within a 50-mile radius of LLNL (LLNL 2001b). Health of individuals living here is favorable (better) relative to California peer counties and the U.S. as a whole (HRSA 2000). Infectious diseases are not common in the county. In fact, over the three year period of 1996, 1997, and 1998, most of the infectious diseases were diarrheal (63 cases from *Escherichia coli*, 809 cases from *Salmonella spp.* and 441 cases from *Shigella spp.*) associated with either unclean water or improper hygiene and food handling (HRSA 2000). There were also 472 cases of viral hepatitis A (infectious hepatitis), 21 cases of viral hepatitis B (serum hepatitis), 8 cases of the measles virus (Rubeola), and 109 cases of pertussis (whooping cough) reported to Alameda County Health officials (HRSA 2000).

Statewide there are appreciably more cases of infectious diseases. Table 3-2 shows the cases and deaths associated with selected notifiable diseases in the State of California for a four-year period (CDF 2001). These statistics show, for example, that while there were no cases of anthrax for the reported years, there were a few cases of plague (unspecified), psittacosis, Q-fever, brucellosis, tularemia, and typhus, along with a number of more common diseases. Although not on the table, there were 9 hantavirus cases in 1999. Acquired immune deficiency syndrome (AIDS) and venereal diseases are some of the most prevalent infectious diseases in California.

3.3.3 Air Quality

Air quality is a measure of the amount and distribution of potentially harmful pollutants in ambient air. Congress passed the *Clean Air Act* (CAA) to mandate that the U.S. Environmental Protection Agency (EPA) regulate those potentially harmful pollutants through the National Ambient Air Quality Standards (NAAQS) for pollutants of concern known as the criteria pollutants. EPA has identified six criteria pollutants: carbon monoxide (CO), sulfur dioxide (SO_2), nitrogen oxides (NO_x), ozone (O_3), lead (Pb), and particulate matter (PM). These pollutants are emitted primarily from combustion sources such as boilers, emergency generators, and motor vehicles. Criteria pollutant emissions data for LLNL have not changed appreciably

The facility is capable of withstanding the g-force predicted for a return period of 1000 years without loss of containment or structural integrity (i.e., Performance Category-2, LLNL 2001c). As a result of conservative assumptions in the design process, damage to the structural systems from a horizontal peak ground acceleration of 0.73 g is expected to be very slight. Nonstructural elements, including ceilings and cladding, could experience minor cracking but would remain secured.

4.2.2.2 Analysis of Abnormal Events and Accidents for Facility Operation

Laboratory-acquired infection. Laboratory-acquired infections are those infections acquired by workers due to the routine performance of their duties. When the exposure to an infectious agent occurs during an event, it is often considered an accident (such as a needle-stick). When the exposure occurs incidentally during contact with a contaminated surface, it is considered a routine health risk. The following discussion deals only with the accidental laboratory-acquired infection.

Many sources were reviewed that compiled laboratory-acquired infection statistics (CDC 1999; Collins 2000; Collins and Kennedy 1999; Pike 1979, 1976; Pike et al. 1965; Sewell 1995; and Sulkin and Pike 1951, 1949). Much of these data are reviewed and discussed in Appendix B, Section B.1. The most recent bibliographic compilation of microbial disease reports (Collins 2000) covers the period from the turn of the century up until August of 2000, and shows a noticeable lack of laboratory-acquired infection reports in the United States during the last ten years. The Department of the Army (DA) *Final Programmatic Environmental Impact Statement, Biological Defense Research Program* (BDRP) (PEIS) (DA 1989) states that since 1976, there have been no occurrences of overt disease in laboratory workers handling infectious organisms within BSL-3- and BSL-4-equivalent BDRP laboratory facilities. The DA estimated the risk to its workers for laboratory-acquired infection for the period from 1970 to 1989 as 0.005 per 1,000,000 person-years (DA 1989). This was a period of heavy activity using large volumes of infectious agents. The incidence of infection appears to be much lower today in large part due to decreased laboratory activity levels since 1968, and in part due to greatly improved preventive measures.

Control of infection in laboratories has achieved a high level of sophistication, to the point that virtually no reports of infection occur in microbiological laboratories. The CDC says that common acceptance of standard laboratory practices indicates that laboratory-acquired infections should be virtually non-existent today (CDC 1999). However, they do still rarely occur and the primary route of exposure is through autoinnoculation by the unintentional injection or needle-stick (Sewell 1995). Needles would be used in the proposed BSL-3 facility. Broken glass with sharp edges could result from accidents with (infrequently used) glassware. Broken glass, needlesticks or even scalpels present a low likelihood of exposure but are obvious when they happen and can be promptly treated with antibiotics, antiviral drugs, or other appropriate medical strategies. The potential for accidental laboratory-acquired infection by these means would be reduced to the improbable level of occurrence.

Since this Environmental Assessment was originally issued in 2002, the CDC has investigated several laboratory incidents involving exposure of personnel to biological agents that resulted in

infection. For example, in November 2004, three cases of tularemia were reported for Boston University laboratory researchers working with the live vaccine strain of *Francisella tularensis* (BPHC 2005). In February 2006, a worker at Texas A&M University was exposed to the select agent *Brucella* during cleaning of an aerosol chamber following an experiment (GAO 2007). Three Texas A&M researchers also tested positive for the bacterium that causes Q fever in April 2006 (Houston Chronicle, 2007). These and other exposures to biological agents during laboratory incidents since 2002 resulted only in treatable illness, and are not known to have resulted in either death or secondary infections. The relatively small number of accidental exposures during this 5-year period supports NNSA's assertion that although it is possible, it is improbable laboratory staff would acquire an accidental laboratory-acquired infection during the operation of the proposed BSL-3.

The Laboratory Release Accident Scenario. The potentially hazardous material to be handled in the proposed facility would consist of infectious microorganisms in containers holding liquid suspensions or on semi-solid media. Accident scenarios usually envisioned for DOE facilities would normally be seen to exacerbate or enhance a release or spread of the hazardous materials, but for the BSL-3 facility would potentially render these materials innocuous (heat, fire, sunlight, and wind). These would be avoided when working with microorganisms and would usually result in microorganisms being killed. Consequently, catastrophic events such as earthquake, fire, explosions and airplane crashes, normally considered as initiating events in DOE radiological or chemical accident analyses, were viewed as having the potential to actually reduce the consequences of microbiological material releases. An earthquake, explosion, or similar event that would result in a breech or rupture of the facility's walls would be bounded by the hypothetical centrifuge-accident analysis of a *Coxiella burnetti* release from the proposed BSL-3 facility structure described later in this section. The probability of catastrophic events (due to earthquake) is already very low. The low probability of an earthquake capable of rupturing the facility containment, coupled with an additionally low probability of such an event occurring during a daytime activity where microorganism containment would be vulnerable, also makes it an unlikely event. The proposed laboratory hypothetical centrifuge accident-release scenario, which itself is very unlikely due to the simultaneous occurrence of several events/conditions that must be combined to produce a release, bounds the catastrophic release scenario. This accident-release scenario is the bounding biological accident-release scenario in the 2005 Sitewide EIS (DOE 2005) for all biological research activities at the Livermore Site. Appendix B provides background information on microbiological accidents. This scenario is also very similar to the BSL-3 accident analyzed in the recently published Final Environmental Impact Statement for the Construction and Operation of the New USAMRID Facilities at Fort Detrick, MD (USAMRMC 2006).

The BSL-3 facility would have only a few operations or activities that would hypothetically place up to 1 liter quantities of material containing infectious organisms at risk at any point in time. These operations or activities would occur at infrequent times and a release to the environment from a catastrophic event would require several simultaneous conditions to coexist: a worker is transferring a quantity of infectious material when the catastrophic event occurs; the containers aren't properly sealed; the entire set of containers is dropped; the containers break open; and the catastrophic event simultaneously causes a structural breach in the BSL-3 containment walls. Engineering and procedural controls minimize opportunities for this

hypothetical scenario. For example, culture samples would be kept in locked freezers or within incubation chambers most of the time and would not become aerosolized in such an event. Therefore, catastrophic events capable of resulting in a substantial release of microorganisms from the confinement of the facility (specifically at greater than infectious dose quantities) would be unlikely to occur.

A literature search and discussions with BSL-3 laboratory regulators and operators (CDC, NIH, and the U.S. Army) revealed no incidents of infectious materials released from catastrophic accidents at microbiological laboratories. According to the U.S. Army (DA 1989), the likelihood of such catastrophic occurrences is too small to be considered as reasonably foreseeable. No such event has occurred in the more than 50 years in which the military has been conducting biological defense research activities (DA 1989). Based on this historical information, this hypothetical scenario was not analyzed further in this EA.

Historical information suggests that other types of accidents would be reasonably foreseeable; these could involve infectious material. Accidents involving the production of aerosols during the use of normal laboratory equipment such as centrifuges, blenders, homogenizers, shakers, sonicators, and mixers are reported. According to *Laboratory-Associated Infections and Biosafety*, this is the second most common route of exposure, the first being laboratory-acquired infection due to needle-sticks (Sewell 1995). Even though these accidents are more frequently reported, they rarely result in workers actually contracting diseases due to the use of vaccines and drug therapies.

Appendix B describes accident scenarios used in other NEPA documents for analysis of BSL facilities. One accident scenario that was analyzed involved the release of a biotoxin from the common soil bacterium *Clostridium botulinum* (BMI 1993). The accident scenario analysis resulted in an estimated potential release of biotoxin that was several orders of magnitude lower than the dose at which "no effect" resulted. Another NEPA document (DA 1996) accident scenario postulated the release of *Brucella spp.* bacteria transmitted by direct contact with animal secretions. The qualitative analysis indicated no release to the public.

Another relevant NEPA accident analysis was prepared by the U.S. Army for its BDRP PEIS covering several facilities across the United States and is considered most relevant to the Proposed Action. The DA has for decades operated a series of the most extensive infectious agent laboratory facilities in the world. This PEIS addresses the entire BDRP, including multiple facilities, and involves a far greater level of operations than NNSA proposes at LLNL. The reason this accident analysis should be considered relevant to the proposed BSL-3 facility at LLNL is because the PEIS analyzed BSL-3 facilities with engineering and operating characteristics similar to those proposed for LLNL, such as similar HVAC system designs for negative pressure and air turnover; the facilities having similar HEPA filtration; the facilities would operate under the same procedures established by CDC (CDC 1999; 32 CFR 627); and the facilities would be designed to handle the same types of microorganisms.

Important differences between the DA's accident analysis modeling and the conditions at the proposed LLNL BSL-3 facility would be due to the model's input parameters (also called modeling assumptions) associated with the meteorological conditions and the proximity to non-involved workers and the public. The DA's accident scenario assumes to have essentially non-

windy site conditions and nearby non-involved facility workers and members of the public. The LLNL site is usually windy and members of the public would usually be a minimum of one-half mile away. The differences in the DA's modeling assumptions and the conditions at LLNL result in the accident analysis being much more conservative for LLNL conditions than the analysis modeled at the DA site. Therefore, the effects of such a scenario, if it were to actually occur, would be much less adverse at LLNL than those hypothesized for a DA site.

The BDRP PEIS accident scenario is referred to as the Maximum Credible Event (MCE) in accordance with the DA's *Biological Defense Safety Program, Technical Safety Requirements* (32 CFR 627). The microorganism chosen for the MCE accident is *Coxiella burnetii (C. burnetii)*, the organism responsible for causing Q fever. According to the *Control of Communicable Diseases Manual* (Benenson 1995), this organism has an unusual stability, can reach high concentrations in animal environments, and is relatively resistant to many disinfectants. The CDC states that *Coxiella burnetii* probably presents the greatest risk of laboratory infection. The organism is highly infectious and remarkably resistant to drying and other environmental conditions. The estimated human infective dose (HID) with a 25 to 50 percent chance of contracting the disease through the inhalation route for Q fever is 10 organisms (CDC 1999).

The rickettsial microorganism, *C. burnetii,* is considered representative of all types of BSL-1, BSL-2, and BSL-3 laboratory microorganisms (bacteria, rickettsia, viruses, fungi, parasites, and prions) because it is highly durable, infectious, and transmissible, and has excellent environmental survivability. Other types of microorganisms were considered for accident scenarios but rejected for specific analysis because they represent a relatively lower human health hazard (fungi and parasites) or have a generally lower environmental survivability (specifically, the prions and viruses). All animal prions and human parasites are Risk Group 1 or Risk Group 2 microorganisms. Only one fungus identified by the CDC requires BSL-3 and all the rest only require BSL-2 or below (CDC 1999). Many viruses require BSL-3 procedures and equipment but cannot survive long in the environment without a host such as a human or other animal. Bacteria and their subcategory, rickettsia, represent a high risk to human health and many require BSL-3 or BSL-4 procedures and equipment.

Of the bacteria, *C. burnetii* is a durable rickettsia that can be handled in the laboratory with little or no loss in viability. It can survive being aerosolized and remain viable, although once separated from a nutrient food source, it dies off at a slow rate. This microorganism can be as infectious as any other microorganism. The CDC reports that exposure to only 10 microorganisms can cause an individual with normal immunocompetency to develop symptoms of disease. Others report this to be as low as five microorganisms or possibly even one (CDC 2001b). *C. burnetii* has the added "advantage" of being one of the CDC "select agents" (42 CFR 72) and is also considered a critical biological agent[26] (CDC 2000a) (also called Bioterrorism agents).

[26] The CDC Strategic Planning Workgroup has prepared a plan to address the deliberate dissemination of biological and chemical agents. Certain organisms are designated as "critical biological agents" and are assigned priority ratings based on characteristics that pose a risk to national security.

The scenario for the MCE (detailed in Appendix B) involves an instantaneous release of a fixed amount of infectious material as follows. A worker uses a BSC to place a 1-L slurry of *C. burnetii* into six 250-ml polypropylene centrifuge tubes. The worker fails to insert the O-rings or tighten the centrifuge caps, which are the screw-on type. The worker takes the tubes out of the BSC and inserts them into a free-standing centrifuge and turns the equipment on. All six tubes leak, with some of the slurry leaking into the rotor, and some leaks into the centrifuge compartment. Most of the slurry that is not aerosolized settles (99 percent) and 90 percent of that which settles becomes droplets inside the chamber. The worker opens the centrifuge and notices the leak. The worker obtains help from two co-workers, and four more workers enter the laboratory not knowing what has happened. The room air exhausts to the outside of the building through a stack on the roof after passing through two sets of HEPA filters that, for conservatism, were estimated to have a filter efficiency of only 95 percent.

For the workers, the accident produces 9,900,000,000 (9.9×10^9) airborne HIDs at a 50 percent rate of contracting the disease (HID_{50} or ID_{50}) which occurs in a 3 ft^3 of space above and around the centrifuge. This volume of contaminated air then disperses throughout the room in response to the ventilation system flow characteristics (for example, the volume of air in the room and the HVAC ducting, and the room air turnover rates). The excited worker who opened the centrifuge is potentially exposed to 100,000 HID_{50} due to a higher rate of respiration at 15 L or 0.5 ft^3 per minute (normal is 4 to 6 L or 0.14 to 0.21 ft^3) (NSC 1996). The two co-workers coming to his assistance receive an only slightly lower dose. The other four workers incidentally exposed receive 100 to 300 HID_{50}.

The result to the general public was calculated for this scenario using a gaussian plume dispersion model under relatively calm wind conditions (stronger winds would dilute more readily). At the maximum air-concentration described above, the model predicted less than 1 HID_{50} per liter of air at a distance of 7 ft (2 m) from the stack, less than 0.1 HID_{50} per liter of air at 53 ft (16 m) from the stack, and less than 0.01 HID_{50} per liter of air at a distance of 125 ft (38 m) from the stack. The concentrations dissipate readily after reaching these maximums since the accident scenario resulted in a one-time instantaneous release.

This hypothetical accident can be used as a bounding accident analysis for the Proposed Action LLNL BSL-3 facility. However, it is exceedingly conservative. From a slightly more realistic perspective, there are some aspects of this accident scenario that would significantly lessen the possible outcome to the point that it would not produce even one HID_{50} at the end of the stack in the case of the proposed facility at LLNL. Some of these are:

- Cultures in a centrifuge in their stationary phase (with 10^8 cells per ml) would quickly pack to the bottom of the centrifuge tube and the upper liquid phase that would become aerosolized would have very few cells (depending upon when the accident occurred in the cycle) – therefore the concentration of cells in the aerosol would likely be many orders of magnitude below that used for the analysis (extremely conservative).
- At LLNL (and most small BSL-3 laboratories) normally only two workers would be allowed in a BSL-3 laboratory at a time for safety reasons.
- In an emergency response mode, the responder would enter only after ascertaining the risk and donning appropriate personal protective equipment.

- The worker(s) would have the appropriate prophylaxis available or immunization prior to working in the laboratory and would not become symptomatic.
- If all the room air were doubly HEPA-filtered with each at a minimum of 95 percent efficiency, the overall filtration would be 99.75 percent efficiency (passing through the first filter with 95 percent efficiency would leave 5 percent to pass through and the second filter would remove 95 percent of the 5 percent – resulting in 99.75 percent overall removal efficiency).
- HEPA filtration is rated at 99.97 percent efficient at the most penetrating design point of 0.3 microns using the DOP standard for calibration and measurement which is a uniform size, shape, and non-charged. Removal efficiency is not based upon size alone because there are several physical processes which actually cause the particulate removal. Penetration of larger- or smaller-sized particulates than 0.1 to 0.3 microns (the most penetrating size range) is negligible (less than 0.03 percent). Actual microbes, especially wet, have biofilms on their surfaces, are not uniform in size or shape, agglomerate together, and would not likely penetrate even at 95 percent efficiency because of their physical characteristics.
- The hypothetical accident results of even these extremely small effects rely on compounding of several independent actions whose combined probability of sequential occurrence would be extremely low (o-rings are not inserted, caps not screwed on properly, all six tubes leak, the worker opens the lid not realizing the tubes leaked, the worker gets two other workers to come over and look, and four more enter not knowing what has happened).
- The aerosol efficiency of 0.1% assumed for the scenario is at least one order of magnitude higher than would be likely in a real situation.
- The modeling assumptions (as described in Appendix B) are for the most stable open-terrain conditions and LLNL is both urban and non-open due to the predominance of buildings and trees which increase turbulence and tortuosity (i.e., mixing) and settling.
- Increases in wind speed over the modeled rate of 4.5 mph would increase aerosol dilution while humidity (not considered by the model) enhances the settling of particulates and would also decrease airborne concentrations.
- The normal high rate of air-changes for a laboratory like this would not generate a single "concentrated slug" of aerosolized material to exit the building as proposed in the model.
- Last, but not least, Risk Group 3 agents (those handled in BSL-3 laboratories) are associated with serious or lethal human diseases for which preventative or therapeutic intervention may be available (high individual risk but low community risk).

The conclusion is that members of the public would have a very low likelihood of being exposed to even a small fraction of one HID_{50}. At LLNL, the nearest member of the public is about one-half mile away. Adverse health effects to uninvolved workers in adjacent buildings or the public would be extremely unlikely to develop from this scenario. Similarly, adverse effects to the environment from the accidental release of non-indigenous organisms would be extremely unlikely as well.

4.2.2.3 Transportation Accident

Infectious substances (etiologic agents) in transit on the Nation's highways, railways, and airports are regulated by the U.S. Department of Transportation (DOT) regulations (49 CFR 171, 172, 173, and 178). As a consequence of these regulations, the DOT tracks and reports accidents and, in particular, hazardous materials incident reports. The general population risk report by DOT from 1994 to 1998 from all hazardous materials transportation is 1 in 8,129,000, or as otherwise stated, 0.11 fatalities per million shipments (DOT 2001a). By comparison, the general population risk per year for motor vehicle accidents is 1 in 6,300 or 1.7 deaths per 100 million vehicle miles (161 million kilometers). The number of hazardous materials shipments is about 800,000 per day with at least 10,000 involving waste hazardous materials identified generally as medical wastes and various other hazardous materials. For the hazardous materials category that includes infectious substances, about 80 percent of these shipments are carried by truck with the remainder carried by rail (DOT 1998). There are an estimated 4,300 non-hospital waste generating facilities (laboratories) that are potential generators of medical waste and other kinds of infectious substances including diagnostics specimens. These facilities generate 73,037 tons per year of infectious medical waste and ship about 200 tons (181,000 kg) per day (DOT 1998). Information extracted from the DOT Hazardous Materials Information System (HMIS) database (DOT 2001b) on infectious substances transportation from 1995 to 1999 show that infectious substance incidents are too few to even be ranked. There is, however, an apparent national increase in overall hazardous materials incidents, which rose from 14,700 in 1995 to 17,069 in 1999.

LLNL has never had a biological-material transportation accident (PC 2002). However, an incident occurred in August-September 2005 in connection with a shipment of a collection of vials containing the select agent Bacillus anthracis (anthrax) to two laboratories, one located in Florida and the other in Virginia. At one lab, workers unpacking the shipment discovered that some of the vials had leaked from their primary containers into the inner packaging of the secondary container. However, the material did not escape from the secondary container into the packing material within the tertiary shipping container. Although the unpacking process was conducted in a laboratory, it was not conducted in a Biological Safety Cabinet (BSC), as required, which resulted in five workers being exposed to liquid from the packages while unpacking the secondary containers. These employees received medical treatment as a precaution and there were no adverse health effects. No liquid penetrated the outer shipping container and there was no public release. At the second lab, discrepancies were noted between the shipping inventory and the samples in the container. As required by 42 CFR 73, the recipients of the shipments notified the Centers for Disease Control and Prevention (CDC) of these problems. As a result, the CDC suspended all LLNL transfers of select agents. An NNSA Occurrence report was filed regarding the incident and LLNL issued a full stand-down of all select agent work.

An analysis of the shipping incident resulted in multiple corrective actions to strengthen LLNL's packaging and transportation program for select agents and other bio-hazardous materials at LLNL. Actions taken to prevent recurrence included an expansion of the Select Agent Security Plan, additional training related to packaging and shipping regulations, clarifying roles and responsibilities, a new bio-governance model, and an improved inventory system.

The CDC and the Department of Transportation (DOT) conducted an inspection of the LLNL Select Agent Program in February 2006 in response to this shipping incident. The inspection noted improvements in the management of select agents that were made to address the root causes of the shipping incident. Following the inspections, CDC approved the resumption of select agent transfers to and from LLNL and re-authorized the select agent program at LLNL for an additional 3 years.

The Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) assumed lead responsibility for enforcement of the Select Agent and Department of Transportation Regulations. In a January, 2007 letter, OIG alleged that during these shipments, LLNL violated the transfer requirements of the select agent regulations by failing to comply with the applicable shipping and packaging laws when transferring a select agent. In addition, the OIG also alleged that LLNL failed to comply with security and access requirements by allowing an individual not authorized to have access to select agents to package the shipments of anthrax, and that LLNL's Responsible Official (RO) failed to ensure compliance with the shipping and packaging requirements of the select agent regulations. The individual had been authorized to package shipments before, but this authorization had lapsed and the RO had not requested a reinstatement of her registration prior to this shipment. The Regents of the University of California (UC) agreed to resolve its liability for these alleged violations through a settlement agreement. Under the terms of the agreement, UC agreed to pay the OIG $450,000 to resolve these allegations.

Accidents due to transportation of microorganisms are not expected to increase due to the Proposed Action. The addition of milliliter-quantity samples shipped to and from the BSL-3 facility through federal or by commercial or private courier would not be expected to change the overall incidence of risk of transportation accidents. Samples could consist of cells in media contained within DOT-certified packages. The consequences of such accidents would be anticipated to be minor, based on the historical data.

4.3 Analysis of Threat of Terrorist Activity

Environmental reviews prepared under CEQ implementing regulations and DOE NEPA regulations require a presentation of the environmental impacts of the proposed action and the alternatives in comparative form, thus defining the issues and providing a clear basis for choice among options by the decision-maker. With regard to intentional malicious acts, the assessment should compare potential impacts of acts by a terrorist that could derive from the proposed action, or that could occur with significantly greater probability as a result of the proposed action, to the potential impacts from those that could already occur if research with pathogenic agents requiring BSL-3 level containment is not conducted at LLNL (the "No Action" alternative).

Intentional malevolent acts, such as terrorist acts, do not lend themselves to the type of probability analysis conducted in NEPA documents for accidents (DOE 2002a). For a typical NEPA accident analysis, one would attempt to estimate the likelihood of a particular accident

scenario. If it was high enough to warrant concern, one would then consider the potential consequences and analyze them accordingly. Probabilities for accidents and catastrophic events can often be estimated by studying historical data of similar events. For malevolent acts, probability data is generally unavailable, since in addition to technical feasibility, one would also need to devise a means for assessing and quantifying as a weighting factor the willful intent of a purpose-driven individual or group. Such factors are not subject to estimation, and are likely to vary over time.

Therefore in dealing with the potential for terrorism and its NEPA implications, NNSA has adopted an approach based on that which is used in designing security systems and protective strategies, where one begins with the assumption that a terrorist act will occur, regardless of the actual probability of such an act. Increasing levels of protective strategies are then put into place to reduce the risk of a successful terrorist attack to an acceptable level, and subsequently the potential for the facility to be an attractive target for terrorism. The conclusions of the NNSA in the analysis that follows reflect the influence of that approach.

There is a broad range in malevolent and terrorist act scenarios that have been considered and taken into account in planning the design and operation of this facility. Malevolent acts centered on the facility could be perpetrated by a terrorist who has no other intent and no legitimate connection to the facility, but also by other individuals, including a knowledgeable insider. One could postulate that catastrophic damage to the facility could be accomplished either by air or ground attack or by an individual gaining direct access to the building. Similarly, one could postulate other acts of terrorism such as the covert theft of a sample of pathogenic material, so as to avoid immediate detection or discovery which would activate corrective measures and defeat the motives and intent of the terrorist. Research conducted in the proposed facility would be specifically directed to developing technologies and systems to improve national defense against, and mitigate the consequences of these, and other similar terrorist acts.

As discussed below, because of the safeguards and security measures to be taken, NNSA considers the probability of a successful terrorist act at the LLNL BSL-3 Facility would be extremely low and is not expected during the life of the facility. However, potential impacts of acts by terrorists at the LLNL BSL-3 facility were evaluated. Three types of threats were considered:

1) facility damage or destruction from direct terrorist attacks that results in loss of containment;
2) the theft and subsequent release of a pathogenic material by a terrorist from outside LLNL; and
3) the covert theft and subsequent release of a pathogenic material by an insider with access to the facility.

Each of these scenarios are evaluated and the measures NNSA would implement to counter these threats are described. The potential impacts of these three scenarios were evaluated, including the potential impact that a successful terrorist attack would have.

NNSA believes the probability of a successful terrorist act at the LLNL BSL-3 Facility is very low, and it is not an event expected during the life of the facility. In addition, the Research that

would be conducted in the facility would be directed to developing technologies and systems to improve national defense against bio-warfare and bio-terrorism, and thus increase the nation's ability to mitigate the consequences of terrorist acts in the future.

4.3.1 Facility Damage or Destruction from Terrorist Attacks that Result in Loss of Containment

Deliberate facility damage with the intention of releasing small tube-stored samples or working cultures of pathogenic agents would be possible if an individual were able to gain direct access to the facility or cause a catastrophic breach of all containment systems. For example, a suicidal plane crash could breach the facility's containment. Similarly, an explosive device delivered by a vehicle or an individual on foot could breach facility containment. Depending on the time of day and the type of research underway, a loss of containment could result in a release of pathogenic materials. It is probable that the organic biological material would be destroyed by any resulting fire (DOE 2002b). These types of scenarios at the Livermore Main Site would not be possible under the No Action Alternative as the facility would not exist, and are therefore scenarios unique to the proposed NNSA action.

Impacts of a Release Following Loss of Containment. Catastrophic events such as fire, explosions, and airplane crashes, normally considered as initiating events in NNSA radiological or chemical accidents, have the potential to actually reduce the consequences of microbiological material releases due to the heat produced by these events (DOE 2002b). As discussed below, the consequences of a malicious act designed to breach containment are bounded by the accidents and natural catastrophic events evaluated in the EA because they would result in a similar loss of containment.

During routine operations, very limited quantities of biological agents (such as *C. burnetii*) would be in use, usually only enough to begin cultures in petri dishes. Biological agents would typically be handled in a liquid- or solid -medium container, such as a petri dish or flask, which would release very few organisms to the air if spilled. As noted in Section 4.2.2.1, a few operations or activities could hypothetically place up to 1 liter quantities of a slurry of material containing pathogenic organisms at risk at any point in time. One liter of *C. burnetii* generated in tissue culture would contain a maximum of about 1 trillion bacteria. The remaining material would be stored in freezers. An explosion with a subsequent fire would result in a lower risk than without a fire because much of the biological material available for release would likely burn or be killed by heat rather than released to the environment (DOE 2002b). Breach of containment in the absence of an explosion is likely to rupture containers of disinfectant, such as bleach, which would also reduce the amount of viable agent expected to escape the facility following the attack. Additionally, exposure to several environmental factors could kill many airborne microbes in their vegetative state. These factors include ultraviolet light and dehydration. Together, these factors would account for a substantial reduction in the number of microorganisms released, generally within minutes. Therefore, a terrorist act, such as a plane crash, would not be expected to result in a release of greater magnitude than from other catastrophic events already considered in this document or, for example, from releases that routinely occur during lambing season at numerous local ranches, or from births of other infected

domestic or wild animals. By way of comparison, one placenta from a ewe infected with *C. burnetii* contains about 10^{15} organisms (Welsh et al, 1951).

Risk Group 2 and Risk Group 3 agents proposed for use in the facility cause human diseases for which preventive or therapeutic interventions may be available. Nationally, health care providers have been trained to recognize symptoms of exposures to Risk Group 2 agents (such as anthrax) and Risk Group 3 agents. Local hospitals and health care providers in the Livermore area have been briefed by LLNL medical staff. For agents studied in the BSL-3 facility, prophylactic measures are available in the event of exposure. Individuals could be inoculated to prevent infection or treated to recover from exposure to a known biological agent, just as presently is done in medical facilities across the country when these same biological organisms from natural sources infect members of the general public. There have been a number of reported cases (in 4 selected years) of Q-Fever (18), Tularemia (10), and Plague (3), and other select-agent diseases, from natural and accidental exposures in California (see Table 3-2). Only one death (from Q-Fever) was reported within this group of select-agent diseases. These statistics reflect the widespread availability of diagnostic testing and treatments procedures for typical Risk Group-2 and -3 select agents in case of exposure and infection.

In general, considering the current levels of security awareness and response available, it is probable that if a successful terrorist attack on the facility resulted in the release of a biological agent to the environment, the effects of such a release would be localized in time (hours immediately following the terrorist act) and place (downwind from the BSL-3 facility). As noted, exposed individuals could be inoculated to prevent infection or treated to assist in recovery. For example, studies (DA 1989) reported that if a non-immunized person were exposed to defined aerosols of up to 150,000 pathogenic doses of virulent *C. burnetii*, the disease could be avoided by giving one milliliter of vaccine within 24 hours after exposure and by instituting antibiotic therapy.

Security Measures to Counter Direct Attacks. It is not possible to accurately predict the probability of intentional attacks at LLNL or at other critical facilities, or the nature of these attacks. The number of scenarios is large, and the likelihood of any type of attack is unknowable (DOE 2002a). Nevertheless, in the aftermath of the attacks of September 11, 2001, NNSA reevaluated scenarios involving malevolent, terrorist, or intentionally destructive acts at LLNL in an effort to identify potential security vulnerabilities and assess possible improvements to security procedures and response measures. Security is a critical priority at DOE facilities, and DOE continues to identify and implement measures designed to defend against and deter attacks at its facilities. Substantive details of terrorist attack scenarios and security countermeasures are classified, because disclosure of this information could be exploited by terrorists to plan attacks.

The requirements for possession, use, and transfer of Select Agents (SAs) and toxins in the United States are established in 42 CFR Part 73. Section 73.11 requires facilities subject to the regulations to develop and implement a security plan establishing policies and procedures that ensure the security of areas containing SAs and toxins based on a risk assessment. A risk methodology, agreed to by the University of California /NNSA/Sandia National Laboratories/Department of Energy Risk and Threat Assessment Methodology Working Group,

guides the development of security risk and threat assessments as they relate to LLNL operations. This methodology is still being used under the new LLNL M&O contractor.

The *Biological Risk and Threat Assessment* (BRTA) (LLNL 2005) developed for the BSL-3 facility at LLNL follows the methodology established by the Working Group and uses the DOE Design Basis Threat[27] to examine the potential vulnerabilities of the facility and its operations, and to mitigate risks. The BRTA is an in-depth analysis that focused on the Design Basis Threat and other potential scenarios, such as acts by terrorists or violent activists.[28] The *LLNL Select Agents and Toxins Security Plan* (LLNL 2006) is based on the BRTA and provides an integrated safeguards and security management approach to implementing a protection program for LLNL's SA and toxin use and storage areas in conformance with the SA requirements of 42 CFR Part 73. In addition to general security programs at the LLNL main site, this program encompasses both physical and personnel security aspects as described below.

When compared with other facilities and locations in the environment for which pathogenic agents could be obtained, the LLNL BSL-3 facility is one of the most physically secure against such efforts. Part 73 outlines minimum security requirements for possession and use of select agents and toxins. The key requirements are locking refrigerators and freezers to store select agents, and controlling access to areas where select agents and toxins are stored or used from the public areas of the building.

Several aspects of the layered physical security systems at LLNL exceed the security requirements imposed by Part 73 on similar facilities. There are over 1350 of these facilities nationwide; the majority of which are either academic or clinical/diagnostic facilities (GAO 2007). First, the LLNL site is surrounded by a patrolled security fence with badge-identification required for entry. The LLNL Protective Force Division provides numerous types of protection, including perimeter access control, fixed access and surveillance points, random vehicle patrols, and an armed response force. The Protective Force Division conducts periodic drills and training to maintain its effectiveness. In March 2004, DOE's Office of Safeguards and Security Evaluations completed a comprehensive review of LLNL security programs and rated the protective force operations as "Effective Performance," which is the highest rating possible.

Building 368 is inside the LLNL protected perimeter. In addition, access to Building 368 is controlled by badge identification and limited to employees registered with CDC for work with select agents, authorized by LLNL management, and enrolled in the Select Agent Human Reliability Program. (This program is discussed in Section 4.3.3) Access to individual laboratories is further controlled by an additional personal identification system to only those staff members approved for work during specific shifts. Building and laboratory access are continuously monitored. Finally, all points of access to the facility, including foundation and HVAC access point, have been physically secured against unauthorized entry. Motion detectors have also been installed in the laboratories and mechanical rooms. Within the facility's laboratories, all select agents are kept in locked freezers when not in use.

[27] The Design Basis Threat identifies credible threats that are postulated for the purpose of analyzing security programs, systems, components, equipment, information, or material.

[28] A violent activist is defined in the Design Basis Threat as an individual who commits violent acts out of opposition to Department programs for ideological or other reasons.

4.3.2 Theft and Subsequent Release of a Pathogenic Material by a Terrorist from outside LLNL

The CDC defines a bioterrorism attack as "the deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death in people, animals, or plants." The CDC recognizes that terrorists may consider using biological agents because they can be extremely difficult to detect and some may not cause illness immediately. The CDC separates bioterrorism agents into three categories depending on how easily they can be spread and the severity of effects they cause. "Category A" agents are considered the highest risk. These agents include organisms or toxins that pose the highest risk because:

- they can be easily spread or transmitted from person to person;
- they result in high death rates and have the potential for major public health impacts;
- they might cause panic and social disruption; and
- they require special actions for public health preparedness.

As noted in other sections of this EA, several Risk Group-2 and Risk Group-3 organisms which may be handled and stored in the BSL-3 facility at LLNL are Category A agents (See Appendix A.3, Table A-1). These agents are routinely handled and stored at over 250 BSL-3 facilities in the United States, and in hospitals that specialize in infectious disease treatment.

Evaluation of the potential terrorist threat that could result from the presence of pathogenic agents in the BSL-3 facility is fundamentally different from that associated with threats to nuclear materials and other hazardous materials at a nuclear facility. As opposed to materials such as spent nuclear fuel rods or special nuclear material, pathogenic agents studied in a BSL-3 facility are usually zoonotic organisms that are present in many locations and occur widely in domestic and wild animal stocks. As such, these agents are already obtainable from the environment. For instance, anthrax (*B. anthracis*, a Risk Group 2 agent) can be found near certain sheep raising operations. The organism causing Q fever, *Coxiella burnetii*, (a Risk Group 3 agent requiring BSL-3- level protection and handling procedures) also occurs in livestock animals. Coxiella burnetti organisms are found in huge numbers in birth fluids, especially amniotic fluid, placenta (up to 10^{12}/g), and fetal membranes of parturient ewes, goats, or cows (Stocker, 1955). Valley Fever in is commonly contracted in California as a result of breathing airborne dust containing *Coccidioides immitis,* a Risk Group 3 fungus readily found in soil throughout most of the Central Valley. Hantavirus is can be found in disused buildings containing wild mice feces. Plague is caused by *Yersinia pestis*, which is endemic in rodent populations throughout the Sierra Nevada mountains. The organism that causes rabbit fever, *Francisella tularensis*, derives its name from Tulare County, just one of the counties in California where the organism is prevalent. Thus, a knowledgeable terrorist could collect environmental samples of many Risk Group-2 or Risk Group-3 microorganisms and grow large quantities of them for dissemination without attacking or stealing from a government or private BSL-3 facility. This is clearly different than the analogous risk to the security of high-level radioactive spent fuel rods at a nuclear power plant, as those "source materials" are uniquely concentrated radioisotopes that are not readily obtainable or producible and cannot be "grown" to larger volume from a minute sample.

The most serious ultimate potential impacts of a terrorist act using material stolen from the LLNL BSL-3 facility would be similar to those that could occur should a terrorist collect the same organisms from infected livestock, wild animals or the locations in the environment where they occur naturally. Because these and other pathogenic organisms to be studied in the proposed BSL-3 facility are typically collected from environmental samples in the first place, they are just as accessible to a technically-competent terrorist (or group) as to any legitimate researcher. As such, the proposed action does not measurably add to the avenues already available to a terrorist for obtaining pathogenic materials or measurably increase the likelihood of this type of malicious act. Therefore, the facility is not considered an attractive target for an outside terrorist. Because a malicious individual could already obtain pathogenic material by other methods under the No-Action ("status quo") Alternative, the presence of pathogenic agents in the proposed, highly secured BSL-3 facility would not pose any new or greater risk to human health or the environment from an outside terrorist or terrorists than already accrues without operation of the BSL-3 facility at LLNL.

4.3.3 Covert Theft and Subsequent Release of a Pathogenic Material by an Insider with Access to the Facility

Although not expected to occur due to stringent personnel security and screening programs at LLNL, surreptitious removal of a small vial containing a few milligrams of a select agent, or material swabbed from a vial, could be accomplished by a motivated, technically competent insider with access to the locked storage freezers. Following theft, five essential steps need to be accomplished in order to cause large numbers of human health impacts using the stolen organism:

One must obtain the appropriate strain of the pathogen;
One must know how to handle the organism;
One must know how to grow it in a way that will produce the appropriate characteristics;
One must know how to store the culture and to produce sufficiently large quantities; and
One must know how to prepare and disperse the agent properly.

In addition, the material must be managed in a way that maintains the virulence or infectivity during production, storage, transportation and dispersion. Accomplishing these requirements was difficult even for long-term and well-funded programs in the former Soviet Union and other state-run programs.

Once offsite, the initial stolen swab or sample could be cultured to increase the amount available for use in an attack against the public. As noted above, refining the cultured product to obtain a highly dispersible form of the select agent requires a high degree of technical skill and specialized equipment. However, a dispersible form of *B. anthracis* was distributed through the U.S. Postal Service in 2001. As a result of this attack, 22 people were infected and 5 people died. Assuming a highly technically competent individual (or group) was successful in obtaining pathogenic material, and given general constraints such as access and use of a single biosafety cabinet in a general laboratory setting, it might be possible to grow quantities of dispersible *B. anthracis* similar to those released in 2001 (although it has never been officially confirmed, the New York Times reported in 2002 that the amount in one of the 4 letters was 0.871 grams

[Broad and Johnston, 2002]). This material could then be distributed through the U. S. Postal Service in local major cities such as Oakland or San Francisco to the public or elected officials.

Impacts of a Theft and Subsequent Release of a Pathogenic Material. As shown in 2001, dramatic human health impacts and economic disruption can result following the release of pathogenic materials. If a terrorist was able to obtain material from any source, refine the material to a dispersible form, and then disperse it through mechanisms such as the postal service. One could assume that tens of people could be infected and a few unsuspecting or untreated people might die. However, limitless other scenarios could be postulated involving greater amounts, different agents and different pathways such as air, water or food. Some scenarios could have greater consequences (e.g., use of larger quantities), and some of which would have lesser consequences (e.g., agent dilution and partial or complete destruction upon release to air, water, or food environments as the transport mechanism). Taken to extremes, one can even postulate scenarios with catastrophic implications. (SNL/LLNL, 2006)

Since the 2001 letter attacks, emergency response systems have been put into place to respond to a release of biological agents in the U.S. Postal Service and other means that might be used for dispersal. The Postal Service has implemented anthrax-related engineering controls and work practices that reduce the potential for an undetected re-aerosolization event. In other areas, BioWatch, a system designed to detect and locate an aerosol release of a bio-threat organism quickly and accurately enough for an effective response, is now deployed in major cities nationwide under the auspices of the U.S. Department of Homeland Security (DHS). BioWatch laboratories, including LLNL, are part of the Laboratory Response Network operated by the CDC. The continuing LLNL research support to these already-vital National Security programs/systems is one of the reasons the DOE BSL-3 facility at LLNL was proposed; it is considered essential to national defense programs administered by DHS.

Personnel and Inventory Security Measures to Counter Theft of Pathogenic Materials. In addition to physical security measures described above, and as specified in 42 CFR Part 73, persons possessing, using, or transferring select agents and toxins must first:

- successfully pass the Department of Justice Security Risk Assessment;
- be authorized by the HHS Secretary or APHIS administrator; and
- be registered with the CDC.

In addition to these federal requirements, UC also requires that personnel having access to select agents and toxins must enroll in and be approved by the LLNL Select Agent Human Reliability Program (SAHRP). SAHRP is a security reliability program that selects, trains, certifies, and monitors individuals whose work requires unescorted access to select agents and toxins. Personnel in the SAHRP are screened for physical, mental and personality disorders potentially affecting their judgment and reliability, alcohol abuse, use of illegal drugs or the abuse of legal drugs or other substances, or any other condition or circumstances that may be a security concern. In addition to SAHRP approval, personnel must be verified by Laboratory management and approved by the Responsible Official (RO) as having received the appropriate education, training, and experience for access to select agents. (As by 42 CFR Part 73, the RO is the person charged with ensuring compliance with the applicable regulations.) Access to select agents in the BSL-3 facility would be limited to a very small number (generally less than 10) of qualified and cleared employees.

CDC regulations require extensive documentation of activities involving select agents. Only personnel on LLNL's CDC registration are allowed to handle the agents. All access to select agent handling areas would be recorded. Records would be kept every time an individual enters or leaves an area with select agent samples, regardless of how brief a time or how often they do so. Freezers will have logs to record access, transfer, and use of the stored select agents. To satisfy the requirements of 42 CFR Part 73, LLNL's Responsible Official (RO) must ensure that detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins access and operations are maintained. The RO reviews the inventory at least annually.

4.3.4 Overall Risk Assessment

The M & O contract for LLNL, DOE directives, and federal law require that LLNL protect the laboratory and the public against a broad range of terrorist threats and other hostile acts that may cause unacceptable impacts on national security or on the health and safety of employees, the public, or the environment. A multi-level security strategy is used, with measures applied site-wide and at the facility and personnel levels.

Across the site, extensive security measures are in place to detect and repel intrusions consistent with LLNL's mission as a nuclear weapons laboratory. The Biological Risk and Threat Assessment developed for the BSL-3 facility examined the potential vulnerabilities of the facility and its planned operations, and identified additional measures to mitigate risks. This assessment guided the development and implementation of multi-layered and robust security programs

specifically designed to mitigate threats to select agents at the facility. Personnel security policies and practices have been implemented for work with pathogenic agents at LLNL. By denying access to insiders whose backgrounds suggest they are at risk for engaging in unreliable, untrustworthy, or disloyal behavior, these measures provide an additional safeguard against the loss of pathogenic materials.

When these measures are considered together, the probability of a successful terrorist attack at the LLNL BSL-3 facility has been minimized to an extent commensurate with the potential threat. A direct assault of the facility is highly unlikely to succeed, and would have impacts bounded by the catastrophic events already evaluated in Section 4.2. Because pathogenic agents are already available in nature and at other, less secure locations, the risk of an outside terrorist acquiring pathogenic material is not significantly increased by having pathogenic material at LLNL (one of the most secure facilities in the nation). And while the theft of pathogenic materials by an insider from any bio research facility could have very serious consequences, this scenario is not expected to occur at LLNL due to human reliability programs, security procedures, and management controls at the facility and the laboratory.

NNSA believes that the potential for terrorist activity targeting the proposed BSL-3 facility does not result in measurable impacts to human health or the environment. As stated in section 1.3, operation of the facility would support NNSA's mission to "develop, demonstrate and deliver technologies and systems to improve domestic defense capabilities and, ultimately, to save lives in the event of a chemical or biological attack." The work that would be conducted in the biodefense field at the BSL-3 facility would focus on providing both the basic bioscience and the tools necessary to present bioterrorism. Work would be conducted on topics such as detection of biowarfare threats, human and microbial forensics research and applications, and presymptomatic disease detection. LLNL could use this information to develop advanced detection systems to provide early warning, identify populations at risk and contaminated areas, and facilitate prompt treatment. Researchers at the facility would attempt to develop DNA signatures and biological forensics technologies to identify infectious agents, their geographical origin, and initial sources of infection. Similar approaches are applied to human forensics, and are used in both law enforcement and intelligence-gathering activities.

4.4 REMODEL/UPGRADE ALTERNATIVE

Construction: This alternative would mainly be disruptive to the other workers in the building being remodeled or upgraded. The first step would be deconstruction of the identified laboratory. The laboratory room would first be stripped to the bare walls, floor and ceiling. Ducting, plumbing and electrical work would be done next; then new walls would be installed that could be made seamless. This work would be noisy, but periodic exceedance of the OSHA standard would be infrequent, depending upon the specific task. This activity could interrupt research in adjacent laboratories due to the additional dust, vibration, and the effect on electrical or "plumbed" service being periodically shut off. The most difficult task would be air-balancing of the BSC and the effects of activities in the adjacent laboratories.

Operations. The effects of operation would be the same as for the Proposed Action.

4. Protective eyewear should be worn for conduct of procedures in which splashes of microorganisms or other hazardous materials is anticipated.

D. *Laboratory Facilities (Secondary Barriers)*

1. Laboratories should have doors for access control.

2. Each laboratory contains a sink for hand washing.

3. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.

4. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surface and equipment.

5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.

6. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

Biosafety Level 2 (BSL-2)

Biosafety Level 2 is similar to Biosafety Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from BSL-1 in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists; (2) access to the laboratory is limited when work is being conducted; (3) extreme precautions are taken with contaminated sharp items; and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

The following standard and special practices, safety equipment, and facilities apply to agents assigned to Biosafety Level 2:

A. Standard Microbiological Practices

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

2. Persons wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.

10. There are no specific ventilation requirements. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

Biosafety Level 3 (BSL-3)

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents.

All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features.

It is recognized, however, that some existing facilities may not have all the facility features recommended for Biosafety Level 3 (i.e., double-door access zone and sealed penetrations). In this circumstance, an acceptable level of safety for the conduct of routine procedures, (e.g., diagnostic procedures involving the propagation of an agent for identification, typing, susceptibility testing, etc.), may be achieved in a Biosafety Level 2 facility, providing 1) the exhaust air from the laboratory room is discharged to the outdoors, 2) the ventilation to the laboratory is balanced to provide directional airflow into the room, 3) access to the laboratory is restricted when work is in progress, and 4) the recommended Standard Microbiological Practices, Special Practices, and Safety Equipment for Biosafety Level 3 are rigorously followed. The decision to implement this modification of Biosafety Level 3 recommendations should be made only by the laboratory director.

The following standard and special safety practices, equipment and facilities apply to agents assigned to Biosafety Level 3:

A. *Standard Microbiological Practices*

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

2. Persons wash their hands after handling infectious materials, after removing gloves, and when they leave the laboratory.

3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear con tact lenses in laboratories should also wear goggles or a face shield. Food is stored out-side the work area in cabinets or refrigerators designated for this purpose only.

APPENDIX C: **Public Comments on the EA**

C.1 Response to Public Comment Letters/Email Messages

In response to a September 16, 2003 lawsuit filed in Federal District Court challenging the adequacy of the 2002 EA, the Court ruled that the EA was adequate. In response to an October 2006 appeal by the Plaintiffs, the Ninth Circuit concluded that while DOE did take a hard look at identified environmental concerns and that its decision was fully informed and well-considered, the DOE did not consider whether the threat of potential terrorist activity necessitates the preparation of an environmental impact statement and thus remanded the matter to the DOE. In response to this ruling and new DOE guidance, DOE has revised the 2002 EA to consider the potential impacts of terrorist activity. The revised Draft Environmental Assessment (EA) was made available for public comment from May 11, 2007 to June 11, 2007. Over 80 comment responses were received from residents of 8 different states and the District of Columbia.

For this document, the public comment appendix from the 2002 EA has been supplemented to include a summary of additional public comments that provided new information pertinent to the proposed action or expressed concerns that were not previously responded to in the original document. Letters and emails providing comments on the Revised EA are included in Section C.2.

1. NEPA Compliance: Documentation/Review Level.

Several commenters expressed the opinion that a BSL-3 facility at LLNL would allow for experiments with a broad spectrum of biotoxins and biological materials/agents. They believed that this would be a new program for DOE and LLNL that, if inadequately analyzed before proceeding, could endanger the workers and the community. Commenters indicated that the draft EA provided only boilerplate assertions that the risks would be negligible, and relies on adherence to procedures, some of which DOE laboratories have not followed in the past according to the commenters. Consequently, they believe that a further environmental review in the form of a project-specific Environmental Impact Statement (EIS) should be conducted. Some of the same commenters were of the opinion that the proposed project represents an integrated new program area for the DOE, and as such, a Programmatic EIS (PEIS) should be prepared to review the effects of undertaking work in this “new” mission area. Several commenters expressed the opinion that the purpose and need for the proposed action at LLNL is without precedent, and the commenters called for a complete NEPA review (PEIS) of the NNSA Chemical and Biological National Security Program (CBNP) which some referred to as the “Chemical and Biological Nonproliferation Program.”

One commenter expressed the opinion that "… analysis of terrorist risk at a BSL-3 facility is far too significant to be performed using an interim guidance, which does not include the full requirements and which may be changed in the final guidance. DOE/NNSA must withdraw this revised EA and release a second revision of the EA for public review following the finalized guidance."

The characterization of the potential inventory in the BSL-3 by several commenters is in error. LLNL has no plans to have 100 liters of a slurry of biological agents in any single laboratory at any one time. Most research involves a few milliliters of material in growth solution. LLNL plans to store samples of biological agents, including select agents, in small vials, most of which are 2 ml. The facility limit is 25,000 vials, so the maximum volume of the vials is closer to 50 liters, not 100 liters. Typically, less than 2 ml of sample is stored in any vial so the aggregate total volume of all samples would be significantly less than 50 liters. These vials are stored in -80 degree freezers in three separate laboratories in frozen form, not as aggregate liquid slurry. As noted above, only 1 liter would be handled in any laboratory at any one time.

The DOE does not operate a national biological research program. Individual research efforts are managed at DOE sites on behalf of non-DOE sponsors as "Work for Others". The DOE has established a Biosurity Executive Team, a national level working group, to recommend the establishment of biosurity-related policies, regulations, requirements, and standards. This comment will be forwarded to the Chairman of that group for consideration.

4. Compliance with Biological Weapons Convention

A commenter expressed concern that the proposed work would undermine the Biological Weapons Convention and be viewed with suspicion by the world community. Additionally, the commenter remarked that the draft EA gives no indication of how BWC compliance would be instituted. Several commenters were of the opinion that the draft EA does not provide a process to guarantee public scrutiny of the LLNL biosafety committee deliberations and decision making.

Several commenters reiterated concerns that research in this facility could be construed as violation of the Biological and Toxin Weapons Convention since it is located in a secure weapons laboratory and oversight by the Institutional Biosafety Committee (IBC) is less than "transparent".

Response

U.S. participation in the Biological Weapons Convention is discussed under topic 3 above.

The proposed BSL-3 facility would be operated according to all guidance and requirements established by such agencies as the CDC, NIH, USDA, DOE and LLNL. Specific guidance references are detailed in Section 2.1.2 of this EA. NIH guidelines require that an IBC be appointed by an institution to provide local and institutional oversight and approval of potentially hazardous lines of biological research (NIH 2001). Section IV-B-2 of the NIH guidelines establishes procedures that the IBC shall follow in its role of review and approval responsibility. These guidelines include review and approval of applications, proposals, and activities; and making available to the public, upon request, all IBC meeting minutes and any documents submitted to or received from funding agencies that those agencies must make available to the public. As detailed in this EA and in the NIH guidelines, at least two members of the IBC are not affiliated with LLNL and they represent the interest of the surrounding

community with respect to health and protection of the environment. These IBC members may be officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns of the community. Since the IBC is ultimately responsible for ensuring that research conducted at, or sponsored by, LLNL is in compliance with applicable guidelines or regulations, this ensures that the public will be involved in approval of BSL-3 research and review of safety and compliance protocol as it does now for certain BSL-2-level projects. It is possible that some specific project information will be subject to DOE security and classification restrictions, and will consequently not be made available to the public. All proposed microbiological research projects at LLNL, even projects with classified portions, will undergo review and approval by the IBC.

The IBC was established at LLNL in 1991 to ensure compliance with recognized guidelines and regulations concerning research with recombinant DNA or human, animal, and plant pathogens. In 1998, the IBC registered LLNL under the Laboratory Registration and Select Agent Transfer Program of CDC. As currently practiced at LLNL, the IBC must approve all research in the cited subject areas prior to commencement. Details regarding the procedures for choosing committee members and other IBC functions are not within the scope of this environmental review.

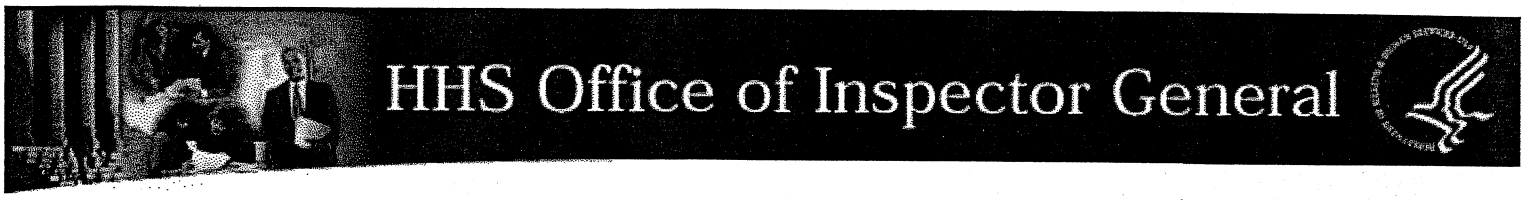
5. Public Health and Safety, and Worker Safety Issues

Comments regarding the issue of public health and safety ranged from general opposition to a BSL-3 facility at LLNL to specific concerns about the potential for accidents and the implementation of procedural safeguards. One commenter remarked that there was no evidence that LLNL conducted a preliminary hazards analysis for the proposed facility and another commenter stated that it was inappropriate to allow biological warfare agent research so close to a major population center. Commenters also expressed the opinion that anticipated work with genetically modified organisms would pose unique or unknown risks to the general public, emergency personnel, and regional medical workers. Commenters expressed concern about how LLNL would respond in the event of an accident at the BSL-3 and how the lab would notify the public and provide information on emergency response actions during an accident.

One commenter remarked that the Draft EA failed to address the effect that a release or exposure could have on the way a region functions. The commenter cited the anthrax attacks of 2001 as an example of the difficulties of determining the nature and extent of a hazard and the potential for entire facilities to close down, despite a relatively small number of casualties. One commenter stated an opinion that the immunization status of laboratory workers represents critical information that should be available to all employees of LLNL and residents of the area.

Comments on the Revised draft EA expressed concern that it does not adequately analyze the health impacts of a release of the the BSL-3 facility's total inventory of up to 100 liters or 25,000 different samples of pathogens.

EXHIBIT 7



Civil Monetary Penalties

False and Fraudulent Claims

2007

In each CMP case resolved through a settlement agreement, the settling party has contested the OIG's allegations and denied any liability. No CMP judgment or finding of liability has been made against the settling

agrees that he or she will not collect from a Medicare beneficiary more than the applicable deductible and coinsurance for covered services. The OIG alleged that the physician created a program whereby the physician's patients were asked to sign a yearly contract and pay a yearly fee for services that the physician characterized as "not covered" by Medicare. The OIG further alleged that because at least some of the services described in the contract were actually covered and reimbursable by Medicare, each contract presented to the Medicare patients constituted a request for payment other than the coinsurance and applicable deductible for covered services in violation of the terms of the physician's assignment agreement. In addition to payment of the settlement amount, the physician agreed not to request similar payments from beneficiaries in the future.

Go to the top of the page

Select Agents and Toxins

2007

October 2, 2007 ▶ Wako Chemicals USA, Inc. (Wako), Virginia, agreed to resolve its liability for an alleged violation of the Select Agent Program. The OIG alleged that Wako violated the program in the following ways: (1) failing to meet biosafety and security standards appropriate for Botulinum neurotoxins; (2) storing packaged, regulated toxins to be shipped in an unsecured, unregistered location before shipping, which allowed unrestricted access to the toxins; (3) having an inadequate incident response plan; and (4) failing to provide and document the required annual select agent training. Under the terms of the settlement, Wako agreed to pay

the OIG $50,000 to resolve these allegations.

September 24, 2007 ▶ The Regents of the University of California, Lawrence Livermore National Laboratory (LLNL), California, agreed to resolve its liability for an alleged violation of the Select Agent Program. The OIG alleged that LLNL transferred vials of anthrax to two laboratories located in Florida and Virginia. During the transfers, anthrax was released from the shipped vials. An investigation of the packaging for the shipments revealed several violations of regulations governing the shipment of anthrax. The OIG specifically alleged that LLNL violated the transfer requirements of the select agent regulations by failing to comply with the applicable shipping and packaging laws when transferring a select agent. In addition, the OIG also alleged that LLNL failed to comply with security and access requirements by allowing an individual not authorized to have access to select agents to package the shipments of anthrax, and that LLNL's Responsible Official failed to ensure compliance with the shipping and packaging requirements of the select agent regulations. Under the terms of the settlement, LLNL agreed to pay the OIG $450,000 to resolve these allegations.

April 30, 2007 ▶ Sigma-Aldrich Corporation (Sigma), Missouri, agreed to resolve its liability for an alleged violation of the Select Agent Program. The OIG alleged that Sigma violated the program by making two unauthorized transfers of select agents. Specifically, Sigma-Aldrich sent 10 mg of Staphylococcal enterotoxins to the University of Pennsylvania, which was not registered with the CDC to possess, use, or transfer this select agent. In addition, Sigma-Aldrich sent 10 mg of Staphylococcal enterotoxins to Scantibodies Laboratory, Inc., without obtaining prior authorization from DSAT for the transfer. Under the terms of the Agreement, Sigma-Aldrich agreed to pay the OIG $25,000 to resolve these allegations.

February 27, 2007 ▶ The Salk Institute for Biological Studies (Salk),

EXHIBIT 8

U.S. Called Lax at Policing Labs Handling Biohazards

By ERIC LIPTON
Published: October 5, 2007

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Correction Appended

WASHINGTON, Oct. 4 — The federal government is failing to supervise properly a greatly expanded network of public and private laboratories handling deadly agents like anthrax and Ebola, Congressional investigators and public health experts testified on Thursday.

At a five-hour hearing called by a House panel looking into conditions at the laboratories, witnesses described a number of troubling incidents, including one last year at Texas A&M University in College Station, Tex., in which university authorities failed to report that a lab worker had been infected with brucellosis, an animal disease.

“We don’t even know where they are, what we got, what we are doing,” Representative Michael C. Burgess, Republican of Texas, said of the growing number of these specialized laboratories financed by the federal government since 2001.

The panel chairman, Representative Bart Stupak, Democrat of Michigan, said, “No one is in charge here.”

Dr. Richard Besser, director of an agency at the federal Centers for Disease Control and Prevention that coordinates terrorism preparedness, testified that federal investigators there had not found any cases in which a regulated pathogen or biological toxin was released outside the lab.

But since 2003, there have been three confirmed releases within laboratories that together sickened five workers, Dr. Besser said. He agreed with Bush administration officials who testified that better federal oversight of the research was needed.

“As a young program, there is a lot we can learn and there is a lot we can do to improve our oversight,” Dr. Besser said.

Anthrax attacks that killed five people and sickened 17 in 2001, along with other concerns about biological terrorism, inspired billions of dollars in federal spending to construct the laboratories and pay for research at them. Researchers and federal health officials concluded that the nation lacked the capacity to investigate or respond to such problems.
.

Since then, the number of biosecurity labs that handle the most contagious and dangerous agents — like Ebola, smallpox and hemorrhagic fevers — has grown, to 15 from five, including one in the planning stages, Keith Rhodes, a Government Accountability Office investigator, testified.

There has been a similar increase in second-tier biocontainment labs, which can also handle very dangerous substances like anthrax and the avian flu and West Nile viruses.

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Go to Complete List »

While the goal has been to increase public safety, the opposite may have happened, Mr. Rhodes said. With more researchers handling the dangerous agents, there is more likelihood of an accident.

“As the number increases, the risk increases,” he said.

Mr. Rhodes said no government agency with jurisdiction over the labs could tell investigators exactly how many second-tier ones were in the United States, demonstrating the paucity of federal oversight.

Part of the problem, Mr. Rhodes and others testified, is that no single federal agency has the authority or resources to oversee properly the laboratories, particularly those that operate without federal funds.

The situation has caused particular concern among officials at the Federal Bureau of Investigation, Mr. Rhodes said, because the laboratories themselves could become sources of agents that might be used in terrorist attacks.

In his testimony before the House panel, the interim president at Texas A&M, Ed Davis, acknowledged that the institution improperly responded to the February 2006 accident involving its worker.

The research assistant had become seriously ill six weeks after exposure to brucellosis, a bacteria that causes an infectious livestock disease. But even after tests confirmed that the experiment had been the cause, it was not reported to federal authorities. After a second accident was documented, earlier this year, the university’s biohazard laboratories were shut down by the disease control centers.

“We made a mistake,” Mr. Davis testified.

Dr. Besser said that since 2001 the federal government had increased its oversight of laboratories, requiring background checks for researchers who have access to dangerous agents and conducting inspections of the federally financed labs on average once every three years.

But he said much more could be done, including a broader review of laboratory documents and more frequent surprise inspections.

Correction: October 23, 2007

An article on Oct. 5 about a Congressional hearing on the federal government’s oversight of public and private laboratories that handle hazardous biological materials referred imprecisely to Dr. Richard Besser, the director of the coordinating office for terrorism preparedness and emergency response at the Centers for Disease Control and Prevention, who testified at the hearing. He is a career civil service employee; he is not a political appointee of the Bush administration.

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To find reference information about the words used in this article, double-click on any word, phrase or name. A new window will open with a dictionary definition or encyclopedia entry.

Past Coverage

City Opens a Secure Lab To Counter Bioterrorism (July 14, 2004)
New Biolabs Stir a Debate Over Secrecy and Safety (February 10, 2004)
ANTHRAX IN MAIL WAS NEWLY MADE, INVESTIGATORS SAY (June 23, 2002)
A NATION CHALLENGED: THE ANTHRAX TRAIL; Labs Are Sent Subpoenas For Samples Of Anthrax (February 27, 2002)

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Laboratories and Scientific Equipment
Anthrax
United States Politics and Government

EXHIBIT 9

Opening Statement of Chairman Bart Stupak
Oversight & Investigations Subcommittee
"Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States"
October 4, 2007

"This is the first of what will likely be several hearings this committee intends to hold to examine the risks associated with the recent proliferation of high-containment biological research laboratories.

"Today's hearing is focused on high-containment bio-laboratories known as BSL-3 and BSL-4 labs in the United States. We anticipate a future hearing will examine the proliferation of high-containment labs outside the United States. Another hearing will examine the Department of Homeland Security's plan to close the Plum Island Animal Disease Center and build a new, $500 million animal research facility elsewhere, including a new BSL-4 lab.

"Our hearing today will focus on the risks associated with the recent increase of domestic BSL-3 and BSL-4 labs. These BSL-3 and BSL-4 labsare the facilities where research is conducted on highly infectious viruses and bacteria that can cause serious injury or death. Some of the world's most exotic and most dangerous diseases are handled at BSL-3 and 4 labs, including anthrax, foot-and-mouth disease, and Ebola fever.

"The accidental or deliberate release of some of the biological agents handled at these labs could have catastrophic consequences. Yet, as we will hear from the Government Accountability Office (GAO), no single government agency has the ultimate responsibility for ensuring the safety and security of these high-containment labs. Moreover, GAO states there is a major expansion in the number of BSL laboratories is occurring both in the U.S. and abroad, but the full extent of that expansion is unknown. No one in the federal government even knows for sure how many of these labs there are in the U.S., much less what research they are doing, or whether they are safe and secure.

"What we do know is that the federal government has been funding the proliferation of these labs on an unprecedented scale. Over the past five years, NIH has spent more than $1 billion on the construction of new BSL-3 and 4 labs. Given the serious risks associated with these labs, we must ask if all these new labs are necessary. Has NIH carefully assessed the need for these labs before writing checks to build them? Would we be better off expanding existing facilities rather than building dozens of new ones? When it comes to BSL-4 facilities – which are those labs that deal with the most serious diseases for which there is no cure – should we significantly limit the number of labs so there are fewer chances for an accidental or intentional release of these most dangerous substances? Has the proliferation of these labs reached a point at which there are so many labs doing this research that you actually increase the chances of a catastrophic release of a deadly disease?

"Apart from the issue of the mushrooming growth of these labs, perhaps the most important question looming over all this is, are these labs safe?

"The most serious accidents so far have occurred outside the U.S., including the death of a Russian lab worker exposed to Ebola, and the SARS infections that sickened several people and killed a lab worker in Asia. Here in the U.S., over the past four years the CDC has received more than 100 incident reports from labs handling select agents. However, there are indications that the actual number of incidents may be much higher. It is also alarming to note that more than a third of the incident reports are from 2007, which begs the question of why there has been such a steep increase in BSL incidents?

"Federal regulations require reports only for incidents involving so-called "select agents," a list of highly dangerous pathogens. But other dangerous biological pathogens are not on the select agent list, such as hanta virus, SARS, and dengue (ding gee) fever. It appears that there is no federal oversight of the possession, use, or transfer of these dreaded diseases, nor is there any requirement that the theft, loss, or release of these agents will be reported to federal officials.

"Even for select agents – which are regulated – there may be a significant amount of under-reporting of laboratory mishaps. A case in point is Texas A&M University. Texas A&M recently reported to the CDC that one of its lab researchers had been infected in 2006 with brucella and that blood tests of three other workers indicated Q fever exposure. They reported these incidents only after one of our witnesses, Edward Hammond of the Sunshine Project, exposed the incidents on his website. The CDC's subsequent investigation of the Texas A&M lab revealed a number of serious violations of the select agent rules, including lost samples, unapproved experiments, a lack of safety training, and lab workers without the an FBI clearance which is required for working with select agents.

"Unfortunately, the CDC's August investigation revealed not only shortcomings on Texas A&M's part, but also shortcomings on the part of CDC's own oversight. It turns out that the CDC had inspected the very same Texas A&M lab prior to the disclosure of these incidents and found only minor problems. This may indicate that the periodic lab inspections that CDC carries out may not be as thorough as one might hope.

"Other recent incidents indicate additional problems presented by these labs. Problems at the CDC's own lab in Atlanta and recent outbreaks of foot-and-mouth disease in the UK linked to a high-containment lab complex at Pirbright illustrate the importance proper laboratory design, construction, and maintenance, in addition to worker training, safety and security.

"The potential human health risks involved in high-containment laboratory biological research deemed that this subcommittee takes a close look at whether these labs are being designed, constructed, and operated safely.

"As I said, this is the first of several hearings the Oversight & Investigations Subcommittee will conduct on high containment biological research laboratories."

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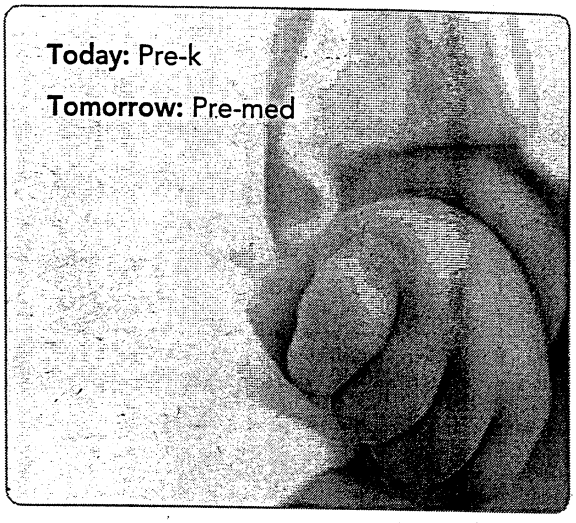
EXHIBIT 10



LIVERMORE

Lab fined $450,000 for mishandling anthrax

Jaxon Van Derbeken, Chronicle Staff Writer
Sunday, October 7, 2007

(10-06) 12:51 PDT (10-06) 12:49 PDT LIVERMORE - --

A former Lawrence Livermore National Laboratory scientist who lacked proper credentials sent off an uninspected package containing two open vials of deadly pathogen anthrax across the country in 2005, triggering a $450,000 federal fine against the lab, authorities say.

The scientist, who resigned her post at the Livermore lab after the incident, left the twist caps off two containers and a loose cap on a third vial in a 1,025-vial shipment to Palm Beach, Fla., in September 2005, according to the findings of a federal agency's review that led to the fine.

The lab in Florida then opened the anthrax shipment without proper precautions, and two of its workers were possibly exposed. The workers were treated with the antibiotic Cipro for a week, then returned to work.

A second shipment of about 3,000 vials made the next day by the same Lawrence Livermore scientist to a lab in Virginia had more vials than it should have, a separate violation of packaging restrictions. The scientist's official credentials vouching for her ability to ship the pathogen had lapsed at the time of the shipments.

The fine was levied against the University of California - the former manager of the lab - as part of a recently reached negotiated settlement that became public at a congressional hearing about the safety of the government's pathogen research programs. A key finding was that lab officials failed to inspect the shipments to ensure they were properly packaged and that labeling accurately reflected the contents.

Lab spokeswoman Susan Houghton said no anthrax leaked from the vials in the Florida shipment, and that the inner packaging would have trapped any anthrax if it had.

However, the government summary of the incident concluded: "During the transfers, anthrax was released from the shipped vials."

Houghton said the lab has made a total of 30 shipments in the last six years without other incident. She noted that the 2005 case led to a seven-month shutdown of all the lab's anthrax-related research for an audit, reorganization and retraining. In April 2006, the lab earned a three-year renewal of its registration to handle biological agents.

A citizen group, Tri-Valley CAREs, seized on the incident as an example of the danger to the community posed by the lab, as well as a new lab that has yet to open.

Marylia Kelley, the head of the group and who lives across from the lab, said lab officials "deliberately withheld important information" and lied about the magnitude of the incident, which was originally described as an inner packaging problem of an unnamed biological agent. It never mentioned anthrax.

"We now know that was a deception," Kelley said in a statement. "The lab disclosed only one aspect of a major accident involving multiple violations of law and regulation and resulting in the release of a dangerous pathogen."

Houghton said that with the renewal of its registration, the lab has a new oversight system, training and procedures. She said the federal Department of Transportation concluded the problem shipments amounted to "an isolated incident."

"The registration allows our laboratory to continue necessary research on behalf of the nation," the lab said in a statement.

E-mail Jaxon Van Derbeken atjvanderbeken@sfchronicle.com.

http://sfgate.com/cgi-bin/article.cgi?f=/c/a/2007/10/07/BA6RSLIUB.DTL

This article appeared on page **B - 2** of the San Francisco Chronicle

EXHIBIT 11

The Nation; Experts spell out risks of bioagent program; The growth in research meant to keep the U.S. safe is overwhelming the oversight system, a House panel is told.

[HOME EDITION]

Los Angeles Times - Los Angeles, Calif.
Author: Jia-Rui Chong
Date: Oct 5, 2007
Start Page: A.23
Section: Main News; Part A; National Desk
Text Word Count: 590

Document Text

CORRECTION: SEE CORRECTION APPENDED; Biodefense research: An article Friday in Section A about the government's troubles in monitoring biodefense research said the University of California manages the Lawrence Livermore National Laboratory. A consortium called Lawrence Livermore National Security, of which the University of California is one of five members, took over management of the lab from the university on Oct. 1.

Rapid growth in the number of biodefense laboratories researching deadly pathogens has overwhelmed the government's ability to adequately monitor the program, federal investigators told Congress on Thursday.

Officials said the expansion of the program over the last few years, coupled with a lack of training of lab workers and poor reporting of lab accidents, posed a potential threat to national security and public health.

"There are too many [labs] at the moment for the level of oversight that's being provided," said Keith Rhodes, chief author of a preliminary report from the Government Accountability Office on biodefense and emerging diseases research. "It's stretched beyond the ability of the fragmented, decentralized oversight that there is now."

Rhodes also expressed concern that, in a survey of 12 federal agencies, none of them could tabulate a total number of the high- security labs -- known as Bio-Safety Level 3 and 4 labs.

Dr. Richard E. Besser, director of the Centers for Disease Control and Prevention's Coordinating Office for Terrorism Preparedness and Emergency Response, acknowledged that lab oversight could be improved.

"As a young program, there is a lot we can learn," he said.

Besser said it was "critically important" for the government to begin convening a task force to suggest better ways to watch over the now-sprawling biodefense program.

The testimony came during a subcommittee hearing of the House Energy and Commerce Committee that was prompted by several recent laboratory accidents, some of which resulted in human exposure.

It was the first time Congress had held a hearing on the safety and security of biodefense research laboratories.

Since 2003, more than 100 accidents have been reported to the CDC or the U.S. Department of Agriculture, both of which monitor parts of the biodefense research program.

Among the accidents was a release of anthrax during shipping because of improper packing by workers at Lawrence Livermore National Laboratory. The Department of Health and Human Services announced a $450,000 fine Thursday against the University of California, which manages the lab. It was the largest of the 11 fines issued by the inspector general since 2003.

Experts say the accidents are an outgrowth of the increase in biodefense work since the Sept. 11, 2001, terrorist attacks and the still-unsolved anthrax mailings that took place a week later. Five people died and 17 were infected by anthrax spores sent in ordinary- looking letters.

Funding for biodefense research from the National Institute of Allergy and Infectious Diseases has grown dramatically, from $187 million in 2002 to $1.6 billion in 2006.

Rhodes said the FBI was particularly concerned about its burgeoning workload in conducting background checks on scientists applying to work on a group of 72 dangerous pathogens. These "select agents" include the Ebola virus and the plague bacterium Yersinia pestis.

"As the number of laboratories balloons, [the FBI's] workload balloons," he said.

Subcommittee Chairman Bart Stupak (D-Mich.) expressed concern that the list of 72 pathogens was too restricted.

"Federal regulations require reports only for incidents involving so-called select agents," he said. "But other dangerous biological pathogens are not on the select agent list, such as hantavirus, SARS and dengue fever."

--

jia-rui.chong@latimes.com

Credit: Times Staff Writer

EXHIBIT 12

Lawrence Livermore National Laboratory
Institutional Biosafety Committee

IBC Meeting Minutes
November 16, 2005
3:00-4:30
T3703, R1006

Attendees:
IBC Members: Mike Ascher, Ex 6 Karolyn Burkhart-Schultz, Patsy Gilbert (Co-Chair), Joanne Horn, Brynte Johnson (BSO), Mort Mendelsohn, Kris Montgomery, Bill Pereira
Observers: Trish Barbosa, Leslie Hofherr (Alt BSO), and Christine Little
Guests: David Counts, Roy Kamimura, Yong Kim, and Dan Knight
IBC Office: Nancy Wrigley (Administrator)

Welcome and Introductions:
The meeting came to order at 3:02pm and Patsy welcomed the committee.

Review minutes from September 19, 2005. Mort Mendelsohn motioned to accept the minutes, and Brynte Johnson seconds. All approve. Any further comments can be sent to the IBC Office, Nancy Wrigley (wrigley2@llnl.gov).

Patsy asked the members if they knew of anyone interested in being part of this committee. We have lost a few members recently and need to have some new people. Dave Counts was invited to this meeting to get an idea of what this committee does. Dave works in NAI as their Assurance Manager. Ex 6 a new community member was introduced. He works at Livermore High School as the Bioscience Teacher. Leslie Hofherr was introduced as the Alternate BSO working with Brynte Johnson. Leslie comes from UCSF and UCLA where she worked with their IBC's.

Since we are reviewing applications that contain sensitive information, Patsy would like all LLNL employees that are on this committee to be sure their computers are Entrusted. We will be sending minutes and applications through email but they will all be Entrusted. Mike Ascher, representing Biosciences, has a different computer system and is trying to find a way he can be Entrusted as well. The IBC Office will hand deliver everything to him, and our Community Members will receive packages through an overnight courier.

- BSO Report: All Select Agent work has been suspended. Request from both CDC and the LSO asking LLNL to validate the current procedures that are in place for Select Agent work. The CDC sent LLNL a report with 29 points we need to address. We have 30 days to respond because Brynte is the Responsible Official (RO) he will be working these issues and will report back to the committee hopefully at our next meeting (March 2006).

Mort Mendelsohn motioned to adjourn the meeting at 4:45pm, and Kris Montgomery seconds. All in favor.

EXHIBIT 13

DOE F 1325.8
(8-89)
EFG (07-90)

United States Government **Department of Energy**

memorandum

DATE: December 1, 2006

REPLY TO ATTN OF: Office of NEPA Policy and Compliance (ECohen: 202-586-7684)

SUBJECT: Need to Consider Intentional Destructive Acts in NEPA Documents

TO: DOE NEPA Community
(list attached)

In light of two recent decisions by the United States Court of Appeals for the Ninth Circuit, DOE National Environmental Policy Act (NEPA) documents, including environmental impact statements (EISs) and environmental assessments (EAs), should explicitly address potential environmental consequences of intentional destructive acts (i.e., acts of sabotage or terrorism). This interim guidance has been developed by the Office of NEPA Policy and Compliance, in consultation with the Assistant General Counsel for Environment and the Deputy General Counsel of the National Nuclear Security Administration. More detailed guidance on this matter is in preparation.

The more recent of the court's two decisions involved DOE's EA for *Construction and Operation of a Biosafety Level-3 Facility at Lawrence Livermore National Laboratory* (DOE/EA-1442, 2002). In that October 16, 2006, decision, *Tri-Valley CAREs v. Department of Energy*, the court wrote:

> Concerning the DOE's conclusion that consideration of the effects of a terrorist attack is not required in its Environmental Assessment, we recently held to the contrary in *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Commission*, 449 F.3d 1016 (9th Cir. 2006). In *Mothers for Peace*, we held that an Environmental Assessment that does not consider the possibility of a terrorist attack is inadequate. Id. at 1035. Similarly here, we remand for the DOE to consider whether the threat of terrorist activity necessitates the preparation of an Environmental Impact Statement. As in *Mothers for Peace*, we caution that there "remain open to the agency a wide variety of actions it may take on remand [and]. . . [w]e do not prejudge those alternatives." Id.

A summary of the court's decision in *Mothers for Peace* is contained in DOE's NEPA *Lessons Learned Quarterly Report*, September 2006, page 19 (available on the DOE NEPA website at *www.eh.doe.gov/nepa* under Lessons Learned Quarterly Reports).

Each DOE EIS and EA should explicitly consider intentional destructive acts. This applies to all DOE proposed actions, including both nuclear and non-nuclear proposals.

Partial guidance on analyzing intentional destructive acts in NEPA documents is contained in *Recommendations for Analyzing Accidents under NEPA* (July 2002;

available on the DOE NEPA website under Selected Guidance Tools). This guidance includes example language and a discussion of ways to apply an analysis of accidents to an analysis of the potential consequences of acts of sabotage or terrorism. This approach may be appropriate for many, if not most, situations where the potential sabotage or terrorist scenarios and the accident scenarios involve similar physical initiating events or forces (e.g., fires, explosions, drops, punctures, aircraft crashes). This approach may not be adequate for all situations, however, because accident scenarios may not fully encompass potential threats posed by intentional destructive acts. For example, this approach may not adequately reflect the threat assessments for facilities with inventories of special nuclear materials. Each EIS and EA should explicitly consider whether the accident scenarios are truly bounding of intentional destructive acts. Regardless of whether additional analysis is necessary, each EIS and EA should contain a section demonstrating explicit consideration of sabotage and terrorism.

The Department is developing new guidance on considering intentional destructive acts in NEPA documents, and expects that the guidance will address such topics as:

- Determining the appropriate level of detail for analysis, consistent with the "sliding-scale" principle (e.g., a more detailed threat analysis is appropriate for a special nuclear material management facility, or for a non-nuclear facility with a significant amount of material at risk; a less detailed analysis may be adequate for a proposed office complex).
- Determining when a finding of no significant impact for an EA is appropriate in view of potential large impacts from terrorist acts.
- Determining what information regarding analyses of these threats can be released to the public.
- Considering intentional destructive acts even when some or all of the analyses may be classified; protecting classified security information through the use of classified appendices and unclassified summaries.
- Timing considerations for cases where threat analyses are needed.

While this further guidance is in preparation, DOE NEPA practitioners should immediately implement the guidance in this notice to explicitly consider the potential impacts of intentional destructive acts in NEPA documents, and should consult with the Office of NEPA Policy and Compliance and, depending on the organization that is preparing the NEPA document, either the DOE or NNSA Office of the General Counsel.

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EXHIBIT 14

ASSESSING THE BIOLOGICAL WEAPONS AND BIOTERRORISM THREAT

Milton Leitenberg

December 2005

followed immediately afterwards. U.S. Government officials worked hard to spread their view to other countries. An edifice of institutes, programs, conferences, and publicists has grown up which continue the exaggeration and scare-mongering. In the last year or two, the drumbeat had picked up. It may however become moderated by the more realistic assessment of the likelihood of the onset of a natural flu pandemic, and the accompanying realization that the U.S. Government has been using the overwhelming proportion of its relevant resources to prepare for the wrong contingency.

Others see exaggeration as necessary in order to prompt preparation. They acknowledge the exaggeration but argue that political action, the expenditure of public funds for bioterrorism prevention and response programs, will not occur without it. "Bioterrorism" may come someday if societies survive all their other impending crises. However, the persistent exaggeration is not benign: it is almost certainly the single greatest factor in provoking interest in BW among terrorist groups, to the degree that it currently exists, for example, in the al-Qaida organization. Precisely this occurred: Their most senior leadership was provoked by statements regarding bioterrorism and its supposed ease by U.S. officials in 1996-97.

- **Costs of the U.S. biodefense program**. On the grounds of "necessity," the U.S. biodefense research program appears to be drifting into violation of Article 1 of the BWC. There is little question but that U.S. officials would make that judgment of any other nation's biodefense program in which the same kind of work was being carried out as is taking place and is planned by U.S. agencies, or in the case that agencies of another government put forward reinterpretations of the provisions of Article 1 of the BWC so as to imply that work could be done on "defensive" biological weapons. A national-level oversight system to see that BWC compliance is maintained by all projects of the U.S. biodefense program—unclassified, classified, and perhaps yet other "black" projects—does not exist. Should the BWC be weakened further and if other state

programs begin to go down the same research path as the U.S. biodefense program, together with any eventual recourse to BW by nonstate actors, the international regime against the development of biological weapons may be irrevocably damaged.

Policy Recommendations.

The policy recommendations derive directly from the analysis presented in the study, and fall into two groups: 1) threat assessment, and 2) U.S. biodefense program oversight.

Recommendation 1: A thorough national BW threat assessment is necessary, to the degree that the best available information permits. It should be based on the realities of state and nonstate actor capabilities, rather than on hypothetical projections of technological state-of-the-art.

Recommendation 2: Government officials should avoid, and where necessary correct, exaggerated portrayals of the biological weapons threat. Such exaggeration, even if seen as politically useful by some, runs counter to the national interest by stimulating the interest of others in BW development.

Recommendation 3: Federal expenditures for Bioshield I and II—to procure vaccines against BW "select agents"—would very likely be of far greater benefit to the U.S. public if they were redirected to procuring vaccines against pandemic flu strains. Such reconsideration and redirection should be an urgent executive and legislative priority.

Recommendation 4: The U.S. Government should make every effort to strengthen the Biological Weapons Convention, the international treaty regime whose essential purpose it is to maintain the norm against the proliferation of BW. It should do nothing to damage it or reduce its stature or relevance.

EXHIBIT 15

The New York Times
nytimes.com

October 2, 2007

U.S. Labs Mishandling Deadly Germs

By THE ASSOCIATED PRESS

Filed at 11:57 a.m. ET

WASHINGTON (AP) -- American laboratories handling the world's deadliest germs and toxins have experienced more than 100 accidents and missing shipments since 2003, and the number is increasing steadily as more labs across the country are approved to do the work.

No one died, and regulators said the public was never at risk during these incidents. But the documented cases reflect poorly on procedures and oversight at high-security labs, some of which work with organisms and poisons so dangerous that illnesses they cause have no cure. In some cases, labs have failed to report accidents as required by law.

The mishaps include workers bitten or scratched by infected animals, skin cuts, needle sticks and more, according to a review by The Associated Press of confidential reports submitted to federal regulators. They describe accidents involving anthrax, bird flu virus, monkeypox and plague-causing bacteria at 44 labs in 24 states. More than two-dozen incidents were still under investigation.

The number of accidents has risen steadily. Through August, the most recent period covered in the reports obtained by the AP, labs reported 36 accidents and lost shipments during 2007 -- nearly double the number reported during all of 2004.

Research labs have worked for years to find cures and treatments for diseases. However, the expansion of the lab network has been dramatic since President Bush announced an upgrade of the nation's bio-warfare defense program five years ago. The National Institute of Allergy and Infectious Diseases, which funds much of the lab research and construction, was spending spent about $41 million on bio-defense labs in 2001. By last year, the spending had risen to $1.6 billion.

The number of labs approved by the government to handle the deadliest substances has nearly doubled to 409 since 2004. Labs are routinely inspected by federal regulators just once every three years, but accidents trigger interim inspections.

"It may be only a matter of time before our nation has a public health incident with potentially catastrophic results," said Rep. Bart Stupak, D-Mich., chairman of the House Energy and Commerce investigations subcommittee. Stupak's panel has been investigating the lab incidents and will conduct a hearing Thursday.

Lab accidents have affected the outside world: Britain's health and safety agency concluded there was a "strong probability" a leaking pipe at a British lab manufacturing vaccines for foot-and-mouth disease was the source of an outbreak of the illness in livestock earlier this year. Britain was forced to suspend exports of livestock, meat and milk products and destroy livestock. The disease does not infect humans.

Accidents aren't the only concern. While medical experts consider it unlikely that a lab employee will become sick and infect others, these labs have strict rules to prevent anyone from stealing organisms or toxins and using them for bioterrorism.

The reports were so sensitive the Bush administration refused to release them under the Freedom of Information Act, citing an anti-bioterrorism law aimed at preventing terrorists from locating stockpiles of poisons and learning who handles them.

Among the previously undisclosed accidents:

--In Rockville, Md., ferret No. 992, inoculated with bird flu virus, bit a technician at Bioqual Inc. on the right thumb in July. The worker was placed on home quarantine for five days and directed to wear a mask to protect others.

--An Oklahoma State University lab in Stillwater in December could not account for a dead mouse inoculated with bacteria that causes joint pain, weakness, lymph node swelling and pneumonia. The rodent -- one of 30 to be incinerated -- was never found, but the lab said an employee "must have forgotten to remove the dead mouse from the cage" before the cage was sterilized.

--In Albuquerque, N.M., an employee at the Lovelace Respiratory Research Institute was bitten on the left hand by an infected monkey in September 2006. The animal was ill from an infection of bacteria that causes plague. "When the gloves were removed, the skin appeared to be broken in 2 or 3 places," the report said. The worker was referred to a doctor, but nothing more was disclosed.

--In Fort Collins, Colo., a worker at a federal Centers for Disease Control and Prevention facility found, in January 2004, three broken vials of Russian spring-summer encephalitis virus. Wearing only a laboratory coat and gloves, he used tweezers to remove broken glass and moved the materials to a special container. The virus, a potential bio-warfare agent, could cause brain inflammation and is supposed to be handled in a lab requiring pressure suits that resemble space suits. The report did not say whether the worker became ill.

Other reports describe leaks of contaminated waste, dropped containers with cultures of bacteria and viruses, and defective seals on airtight containers. Some recount missing or lost shipments, including plague bacteria that was supposed to be delivered to the Armed Forces Institute of Pathology in 2003. The wayward shipment was discovered eventually in Belgium and incinerated safely.

The reports must be submitted to regulators whenever a lab suffers a theft, loss or release of any of 72 substances known as "select agents" -- a government list of germs and toxins that represent the horror stories of the world's worst medical tragedies for humans and animals.

A senior CDC official, Dr. Richard Besser, said his agency is committed to ensuring that U.S. labs are safe and that all such incidents are disclosed to the government. He said he was unaware of any risk to the public resulting from infections among workers at the high-security labs, but he acknowledged that regulators are worried about accidents that could go unreported.

"If you're asking if it's possible for someone to not report an infection, and have it missed, that clearly is a concern that we have," Besser said.

Texas A&M's laboratory failed to report, until this year, one case of a lab worker's infection from Brucella

bacteria last year and three others' previous infection with Q fever -- missteps documented in news reports earlier this year. The illnesses are characterized by high fevers and flu-like symptoms that sometimes cause more serious complications.

"The major problems at Texas A&M went undetected and unreported, and we don't think that it was an isolated event," critic Edward Hammond said. He runs the Sunshine Project, which has tracked incidents at other labs for years and first revealed the Texas A&M illnesses that the school failed to report.

Rules for working in the labs are tough and are getting more restrictive as the bio-safety levels rise. The highest is Level 4, where labs study substances that pose a "high risk of life-threatening disease for which no vaccine or therapy is available." Besides wearing wear full-body, air-supplied suits, workers undergo extensive background checks and carry special identification cards.

"The risk that a killer agent could be set loose in the general population is real," Hammond said.

In other lab accidents recounted in the reports, the Public Health Research Institute in Newark, N.J., was investigated by the FBI in 2005 when it couldn't account for three of 24 mice infected with plague bacteria. The lab and the CDC concluded the mice were cannibalized by other plague-infested mice or buried under bedding when the cage was sterilized with high temperatures.

The lab's director, Dr. David Perlin, told the AP it would be impossible for mice to escape from the building and said a worker failed to record their deaths.

"I feel 99 percent comfortable that was the case," Perlin said. "The animals become badly cannibalized. You only see bits and pieces. They're in cages with shredded newspaper. You really have to search hard with gloves and masks."

A worker at the Army's biological facility in Fort Detrick, Md., was grazed by a needle in February 2004 and exposed to the deadly Ebola virus after a mouse kicked a syringe. She was placed in an isolation ward called "The Slammer," but the Army said she did not become ill.

In other previously undisclosed accidents:

In Decatur, Ga., a worker at the Georgia Public Health Laboratory handled a Brucella culture in April 2004 without high-level precautions. She became feverish months later and tested positive for exposure at a hospital emergency room in July. She eventually returned to work. The lab's confidential report defended her: "The technologist is a good laboratorian and has good technique."

In April this year at the Loveless facility in Albuquerque, an African green monkey infected intentionally with plague-causing bacteria reached with its free hand and scratched at a Velcro restraining strap, cutting into the gloved hand of a lab worker. The injured worker at the Lovelace Respiratory Research Institute received medical treatment, including an antibiotic.

The National Animal Disease Center in Ames, Iowa, reported leaks of contaminated waste three times in November and December 2006. While one worker was preparing a pipe for repairs, he cut his middle finger, possibly exposing him to Brucella, according to the confidential reports.

A researcher at the CDC's lab in Fort Collins, Colo., dropped two containers on the floor last November,

including one with plague bacteria.

A worker at Walter Reed Army Institute of Research-Naval Medical Research Center in Silver Spring, Md., sliced through two pair of gloves while handling a rat carcass infected with plague bacteria. The May 2005 report said she was sent to an emergency room, which released her and asked her to return for a follow-up visit.

EXHIBIT 16

National Environmental Policy Act

N E P A

RECOMMENDATIONS for ANALYZING ACCIDENTS under the NATIONAL ENVIRONMENTAL POLICY ACT

July 2002

U.S. Department of Energy
Environment, Safety and Health
Office of NEPA Policy and Compliance

With respect to radiological risks, note that the discussion of *Human Health Effects* in *Recommendations* focuses on the effects of low doses of radiation. However, an accident analysis may involve both high and low radiation doses. High absorbed doses (hundreds of rad) delivered over a short period of time may result in a risk of a prompt fatality from non-cancer syndromes (e.g., gastrointestinal syndrome, pulmonary syndrome, or hematopoietic syndrome). Evans et al. (NRC, 1993) provides methods for estimating these early mortality risks.

- ✓ Consider both radiological and non-radiological hazards, commensurate with significance.
- ✓ Use appropriate current dose-to-risk conversion factors that have been adopted by cognizant health and environmental protection agencies.

In addition, the appropriate dose-to-risk conversion factors for estimating impacts at high doses (between about 25 and 100 rem) may not be appropriate at lower doses (less than about 25 rem). For example, the high-dose-to-risk conversion factor in Federal Guidance Report No. 13 (EPA, 1999) is 1.1×10^{-3} fatal cancers per rem; the corresponding low-dose-to-risk conversion factor is 6×10^{-4} fatal cancers per rem. As discussed in *Recommendations*, use current dose-to-risk conversion factors that have been adopted by cognizant health and environmental protection agencies, such as the Environmental Protection Agency and the Nuclear Regulatory Commission. When uncertain, consult the Office of Environment, Safety and Health.

In presenting accident analysis results, be clear about the types of exposure scenarios analyzed to avoid confusion. For example, radiological accident scenarios often involve inhaled or ingested long-lived radioactive materials that result in a persistent dose rate to a person throughout his/her lifetime, the accumulation of which is expressed as a committed effective dose equivalent. The reported committed effective dose equivalent may be a large number (e.g., several hundred rem) that may appear to be a high *acute absorbed* dose. In presenting the results for such scenarios it is important to associate the estimate of committed effective dose equivalent with a time period starting from the exposure event and continuing through the person's lifetime.

3.0 Accident Scenarios and Associated Probabilities/Frequencies

3.1 Scenario Development

Range of Accident Scenarios

The key to informative accident analyses is to develop realistic accident scenarios that address a reasonable range of event probabilities and consequences. The set of accident scenarios considered should serve to inform the decision maker and the public of the accident risks associated with a proposed action and alternatives. DOE should consider accident scenarios that represent the range or "spectrum" of reasonably foreseeable accidents, including low

probability/high consequence accidents and higher probability/(usually) lower consequence accidents. (Attachment 1 discusses a related issue, namely intentional destructive acts.)

Analyze *maximum reasonably foreseeable accidents* to represent potential accidents at the high consequence end of the spectrum. A maximum reasonably foreseeable accident is an accident with the most severe consequences that can reasonably be expected to occur for a given proposal.[2] Such accidents usually have very low probabilities of occurrence. As noted above, however, the accident analysis normally should not end with the analysis of maximum reasonably foreseeable accidents.[3]

For most proposals, DOE also should analyze other accidents in the "spectrum" because they may contribute importantly to, or even dominate, the accident risks. In some cases other accidents along the spectrum with lesser consequences than the maximum reasonably foreseeable accident may have an associated significant risk, perhaps a greater risk than the maximum reasonably foreseeable accident. The Cerro Grande fire (see text box on page 8) is an example of such an accident. Analyze a sufficient range of accidents to adequately inform about the accident risks of the proposed action and alternatives.

- ✓ Analyze the consequences of maximum reasonably foreseeable accidents.
- ✓ Analyze a sufficient range of accidents to adequately inform about the accident risks of a proposed action and alternatives.
- ✓ "Bounding" approaches may be used to streamline analyses and account for uncertainty, but tend to mask differences among alternatives.

In developing accident scenarios, some document preparers compensate for analytical uncertainty by using conservative or "bounding" approaches that tend to overestimate potential impacts. Bounding approaches based on conservative assumptions may have several potential benefits, such as streamlining an analysis when there are many uncertainties and avoiding the need to prepare more realistic analyses when not warranted. Further, bounding analyses may be more defensible than more realistic approaches because they are unlikely to underestimate potential accident consequences. On the other hand, bounding analyses may mask differences among alternatives and be less informative about the potential need for mitigation. Also, excessive conservatism may result in a misleading presentation of accident risks.

Because one purpose of NEPA analysis is to inform the public, consider analyzing an accident scenario in which the public has expressed a keen interest, even when the scenario is not

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[2] Maximum reasonably foreseeable accidents are not the same as "worst-case" accidents, which almost always include scenarios so remote or speculative that they are not reasonably foreseeable and not helpful to a decision maker. Analysis of worst-case accidents is not required under NEPA.

[3] An exception to these general guidelines may exist in circumstances where the consequences of the maximum reasonably foreseeable accident are very small. In that case, analyzing only the maximum reasonably foreseeable accident may provide sufficient information regarding the accident risks of the proposal.

reasonably foreseeable. Do not analyze physically impossible accidents, however. Always explain why a scenario of interest to the public was excluded from analysis.

Scenario Probabilities

An accident scenario involves a postulated initiating event followed by a sequence of other events or circumstances that result in adverse consequences. If these subsequent events always occur when the initiating event occurs (i.e., the subsequent events have a conditional probability of 1, given that the initiating event occurs), then the probability (or frequency) of the entire accident scenario is that of the initiating event. Otherwise, the scenario probability would be the product of the initiating event probability and the conditional probabilities of the subsequent (presumed independent for purposes here) events, given that the initiating event has occurred.

Conservatisms

In accident analyses, as with many aspects of environmental analysis in NEPA documents, preparers need to make judgments about the appropriate degree of conservatism to apply. In applying the sliding scale principle to making such judgments, preparers should consider the fundamental purposes of the analysis as discussed above, the degree of uncertainty regarding the proposal and its potential impacts (see further discussion of uncertainty below), and the degree of technical controversy. Accident analyses under NEPA should be realistic enough to be informative and technically defensible.

Consistent with CEQ regulations, avoid scenarios that are based on pure conjecture (40 CFR 1502.22). Specifically, avoid compounding conservatisms – evaluating a scenario by using conservative values for multiple parameters will yield unrealistic results.

- ✓ Apply the sliding-scale principle in making judgments about the appropriate degree of conservatism.
- ✓ Avoid scenarios that are based on pure conjecture (40 CFR 1502.22).

For example, in air dispersion modeling, it is nearly always unrealistic to assume only extremely unfavorable meteorological conditions; prevailing (median) meteorological conditions generally should be used. In exceptional cases (e.g., when there is heightened controversy regarding accident risks or to enable a comparison with analysis in another document), it would be appropriate to estimate and present accident consequences for both median conditions and unfavorable conditions. Median conditions are often defined by using 50% meteorology, which represents plume concentrations that are not exceeded 50% of the time for a given direction and distance or receptor location, and are often characterized by stability class D and moderate wind speeds. (Fifty percent meteorology should not be confused with annual average meteorology. The latter is appropriate for estimating the impacts of normal operations or expected occurrences, but is generally not appropriate for estimating the consequences of accidents.) Unfavorable conditions

should define this population and its maximally exposed member(s) in light of the specific facts and circumstances of each proposal. Attachment 2 regarding application of sliding scale principles also applies to noninvolved workers.

- ✓ Always consider impacts on involved and noninvolved workers.
- ✓ Define the noninvolved worker population and its maximally exposed member(s) for each alternative.

In many cases, a simple population impact estimate using an air dispersion model that considers the expected population between a location near the point of release (typically about 100 meters from the release point, depending on the circumstances) and the site boundary will be sufficient. In some cases, however, sub-populations of workers at the site may warrant specific consideration. Following are examples of sub-populations:

- Other workers in the same building or facility, or its immediate environs, in which an action is proposed
- Workers in buildings or locations immediately adjacent to the proposed project location (Where members of the public typically would be present in areas adjacent to noninvolved workers, such as child care centers, cafeterias or visitor centers, discuss whether accident impacts on such members of the public would be comparable to those estimated for noninvolved workers.)
- For large DOE sites with multiple facilities or geographically separate operational areas, the workers in specific downwind facilities or operational areas
- Specific classes or categories of workers that may be of special interest (See, for example, *Protection of Collocated Workers at the Department of Energy's Defense Nuclear Facilities and Sites* (DNFSB, 1999), which defines classes of populations applicable to hazardous nuclear facilities, including "collocated workers," "immediate workers," "other on-site worker personnel," "transient on-site personnel," and "off-site personnel.")

This guidance does not intend that analysis of impacts on all of these sub-populations is required, or that explicit analysis of any of the sub-populations is usually warranted in accident analyses under NEPA. Consider case-by-case, in accordance with the sliding scale principle, whether potential impacts on specific sub-populations of workers at the site and their maximally exposed members should be analyzed in light of the degree to which they may be harmed.

5.3 Accidental Contamination and Other Indirect Impacts

In evaluating the effects of an accident, characterize the degree to which buildings, land, and environmental media would be contaminated, and describe (at least qualitatively) the potential health and environmental effects from such contamination, including direct and indirect effects associated with potential cleanup activities. To the extent that such effects are not remote and speculative, and as appropriate in accordance with a sliding scale approach, consider the

EXHIBIT 17

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

For Release on Delivery
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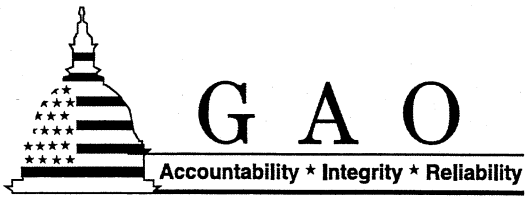
HIGH-CONTAINMENT BIOSAFETY LABORATORIES

Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States

Statement of Keith Rhodes, Chief Technologist
Center for Technology and Engineering
Applied Research and Methods



October 4, 2007

HIGH-CONTAINMENT BIOSAFETY LABORATORIES

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GAO Accountability·Integrity·Reliability

Highlights

Highlights of GAO-08-108T, a testimony before the Subcommittee on Oversight and Investigation, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

In response to the global spread of emerging infectious diseases and the threat of bioterrorism, high-containment biosafety laboratories (BSL)–specifically biosafety level (BSL)-3 and BSL-4–have been proliferating in the United States. These labs—classified by the type of agents used and the risk posed to personnel, the environment, and the community—often contain the most dangerous infectious disease agents, such as Ebola, smallpox, and avian influenza. This testimony addresses (1) the extent to which there has been a proliferation of BSL-3 and BSL-4 labs, (2) federal agencies' responsibility for tracking this proliferation and determining the associated risks, and (3) the lessons that can be learned from recent incidents at three high-containment biosafety labs. To address these objectives, GAO asked 12 federal agencies involved with high-containment labs about their missions and whether they tracked the number of labs overall. GAO also reviewed documents from these agencies, such as pertinent legislation, regulation, and guidance. Finally, GAO interviewed academic experts in microbiological research.

To view the full product, including the scope and methodology, click on GAO-08-108T. For more information, contact Keith Rhodes at (202) 512-6412 or rhodesk@gao.gov.

What GAO Found

A major proliferation of high-containment BSL-3 and BSL-4 labs is taking place in the United States, according to the literature, federal agency officials, and experts. The expansion is taking place across many sectors—federal, academic, state, and private—and all over the United States. Concerning BSL-4 labs, which handle the most dangerous agents, the number of these labs has increased from 5—before the terrorist attacks of 2001—to 15, including at least 1 in planning stage. Information on expansion is available about high-containment labs that are registered with the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture's (USDA) Select Agent Program, and that are federally funded. However, much less is known about the expansion of labs outside the Select Agent Program, as well as the nonfederally funded labs, including location, activities, and ownership.

No single federal agency, according to 12 agencies' responses to our survey, has the mission to track the overall number of BSL-3 and BSL-4 labs in the United States. Though several agencies have a need to know, no one agency knows the number and location of these labs in the United States. Consequently, no agency is responsible for determining the risks associated with the proliferation of these labs.

We identified six lessons from three recent incidents: failure to report to CDC exposures to select agents by Texas A&M University (TAMU); power outage at the CDC's new BSL-4 lab in Atlanta, Georgia; and release of foot-and-mouth disease virus at Pirbright in the United Kingdom. These lessons highlight the importance of (1) identifying and overcoming barriers to reporting in order to enhance biosafety through shared learning from mistakes and to assure the public that accidents are examined and contained; (2) training lab staff in general biosafety, as well as in specific agents being used in the labs to ensure maximum protection; (3) developing mechanisms for informing medical providers about all the agents that lab staff work with to ensure quick diagnosis and effective treatment; (4) addressing confusion over the definition of exposure to aid in the consistency of reporting; (5) ensuring that BSL-4 labs' safety and security measures are commensurate with the level of risk these labs present; and (6) maintenance of high-containment labs to ensure integrity of physical infrastructure over time.

Summary of Known BSL-4 Labs in the United States by Sector

Sector	Before 1990	1990-2000	2001-Present	Total
Federal government	2	1	6	9
Academic	0	1	3	4
State	0	0	1	1
Private	0	1	0	1
Total	**2**	**3**	**10**	**15**

Source: GAO analysis based on open source information.

No Federal Agency Has the Mission to Track High-Containment Labs in the United States

No single federal agency has the mission to track and determine the risk associated with the expansion of BSL-3 and BSL-4 labs in the United States, and no single federal agency knows how many such labs there are in the United States. Consequently, no one is responsible for determining the aggregate risks associated with the expansion of these high-containment labs.

None of the federal agencies that responded to our survey indicated that they have the mission to track and know the number of BSL-3 and BSL-4 labs within the United States (see table 4).

Table 4: Federal Agencies' Mission to Track and Know the Number of All BSL-3 and BSL-4 Labs within the United States

Agency	Mission to track	Know the number
Department of Commerce	No	No
Department of Defense	No	No
Department of Energy	No	No
Department of Health and Human Services	No	No
Department of Homeland Security	No	No
Department of Interior	No	No
Department of Justice	No	No
Department of Labor	No	No
Department of State	No	No
Department of Veterans Affairs	No	No
Environmental Protection Agency	No	No
U.S. Department of Agriculture	No	No

Source: GAO Survey of Federal Agencies Involved with BSL-3 and BSL-4 Labs, 2007.

Some federal agencies do have a narrow mission to track a subset of BSL-3 and BSL-4 labs, and they do know the number of those labs. For example, the CDC and USDA together know the number of high-containment labs working with select agents because, by federal regulation, such labs are required to register with them. But these regulations only require that the entities registering with the Select Agent Program do a risk assessment of their individual labs. No agency, therefore, has the mission to determine the aggregate risks associated with the expansion of high-containment labs that work with select agents. According to the federal agency officials, the oversight of these labs is fragmented and relies on self-policing.